EXHIBIT A

SINCE 1828

sense

noun

Save Word

\ ˈsen(t)s \

Definition of *sense*

(Entry 1 of 2)

1 **:** a meaning conveyed or intended **:** import, signification especially **:** one of a set of meanings a word or phrase may bear especially as segregated in a dictionary entry
2a **:** the faculty of perceiving by means of sense organs
b **:** a specialized function or mechanism (such as sight, hearing, smell, taste, or touch) by which an animal receives and responds to external or internal stimuli
c **:** the sensory mechanisms constituting a unit distinct from other functions (such as movement or thought)
3 **:** conscious awareness or rationality —usually used in plural finally came to his senses
4a **:** a particular sensation or kind or quality of sensation a good sense of balance
b **:** a definite but often vague awareness or impression felt a sense of insecurity a sense of danger
c **:** a motivating awareness a sense of shame
d **:** a discerning awareness and appreciation her sense of humor
5 **:** consensus the sense of the meeting
6a **:** capacity for effective application of the powers of the mind as a basis for action or response **:** intelligence
b **:** sound mental capacity and understanding typically marked by shrewdness and practicality also **:** agreement with or satisfaction of such power this decision makes sense

7 **:** one of two opposite directions especially of motion (as of a point, line, or surface)

sense

verb
sensed; sensing

Definition of *sense* (Entry 2 of 2)

transitive verb

1a **:** to perceive by the senses (see sense entry 1 sense 2)
b **:** to be or become conscious of sense danger
2 **:** grasp, comprehend
3 **:** to detect automatically especially in response to a physical stimulus (such as light or movement)

Synonyms Choose the Right Synonym More Example Sentences Learn More About *sense*

Synonyms for *sense*

Synonyms: Noun

- feel,
- feeling,
- sensation

Synonyms: Verb

- feel,
- perceive,
- scent,
- see,
- smell,
- taste

Visit the Thesaurus for More »

Choose the Right Synonym for *sense*

Noun

sense, common sense, judgment, wisdom mean ability to reach intelligent conclusions. sense implies a reliable ability to judge and decide with soundness, prudence, and intelligence. a choice showing good *sense* common sense suggests an average degree of such ability without sophistication or special knowledge. *common sense* tells me it's wrong judgment implies sense tempered and refined by experience, training, and maturity. they relied on her *judgment* for guidance wisdom implies sense and judgment far above average. a leader of rare *wisdom*

Examples of *sense* in a Sentence

Noun There is an unnerving sense now that technology is driving the culture rather than the reverse. Machines and sites and software are breeding at an exponential clip, and we hapless humans race around trying to adapt. — Steven Johnson, *Discover*, July 2006 The caricature of neurotic nuns who specialized in corporal punishment and guilt crumbles before the countless examples of women religious who made the difference in determining that a

child would eat, or be safe, or have any sense of dignity at all. — Luke Timothy Johnson, *Commonweal*, 22 Sept. 2006

See More

Recent Examples on the Web: Noun This makes *sense* when there is a clear threat, but doesn't when there isn't evidence that such a threat exists, as in the case with the body wash. — *Washington Post*, 19 Feb. 2022 Jake David Smith, the delightful high tenor playing Tony, conceives of his guy as a total nerd, which makes *sense*. — Chris Jones, *chicagotribune.com*, 19 Feb. 2022

These example sentences are selected automatically from various online news sources to reflect current usage of the word 'sense.' Views expressed in the examples do not represent the opinion of Merriam-Webster or its editors. Send us feedback.

See More

First Known Use of *sense*

Noun

14th century, in the meaning defined at sense 1

Verb

1598, in the meaning defined at sense 1b

History and Etymology for *sense*

Noun and Verb

Middle English, from Anglo-French or Latin; Anglo-French *sen, sens* sensation, feeling, mechanism of perception, meaning, from Latin *sensus*, from *sentire* to perceive, feel; perhaps akin to Old High German *sinnan* to go, strive, Old English *sith* journey — more at send

Learn More About *sense*

Share *sense*

Post the Definition of sense to Facebook Share the Definition of sense on Twitter

Time Traveler for *sense*

The first known use of *sense* was in the 14th century

See more words from the same century

Dictionary Entries Near *sense*

sensatory

sense

sense cell

See More Nearby Entries

Phrases Related to *sense*

come to one's senses

false sense of security

in a/one sense

Statistics for *sense*

Last Updated

21 Feb 2022

Look-up Popularity

Top 1% of words

Cite this Entry

“Sense.” *Merriam-Webster.com Dictionary*, Merriam-Webster, https://www.merriam-webster.com/dictionary/sense. Accessed 21 Feb. 2022.

Style: MLA
MLA Chicago APA Merriam-Webster
Seen & Heard
People are talking about

More Definitions for *sense*

sense

noun
\ 'sens \

Kids Definition of *sense*

(Entry 1 of 2)

1 **:** a specialized function or mechanism (as sight, taste, or touch) of the body that involves the action and effect of a stimulus on a sense organ
2 **:** awareness arrived at through or as if through the senses He felt a *sense* of danger.
3 **:** a particular sensation or kind of sensation I lost my *sense* of balance.
4 **:** the ability to make wise decisions
5 **:** an awareness or understanding of something a *sense* of humor a *sense* of pride
6 **:** a reason or excuse based on intelligence or good judgment There is no *sense* in continuing.
7 **:** a logical, sensible, or practical thing, act, or way of doing Saving money for the future makes *sense*.
8 **:** a meaning or one of a set of meanings a word, phrase, or story may have

sense

verb
sensed; sensing

Kids Definition of *sense* (Entry 2 of 2)

: to be or become aware of My cat can *sense* the approach of a storm.

sense

noun

\ ˈsen(t)s \

Medical Definition of *sense*

(Entry 1 of 2)

1a **:** the faculty of perceiving by means of sense organs
b **:** a specialized function or mechanism (as sight, hearing, smell, taste, or touch) by which an animal receives and responds to external or internal stimuli
c **:** the sensory mechanisms constituting a unit distinct from other functions (as movement or thought)
2 **:** a particular sensation or kind or quality of sensation a good sense of balance

sense

transitive verb
sensed; sensing

Medical Definition of *sense* (Entry 2 of 2)

: to perceive by the senses

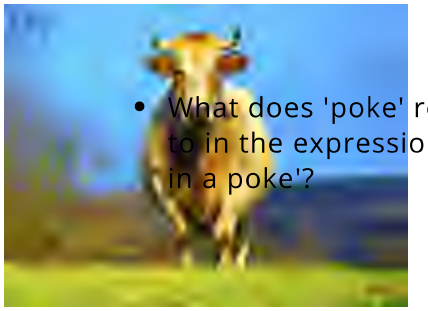
More from Merriam-Webster on *sense*

Nglish: Translation of *sense* for Spanish Speakers

Britannica English: Translation of *sense* for Arabic Speakers

Britannica.com: Encyclopedia article about *sense*

Farm Idioms Quiz



- What does 'poke' refer to in the expression 'pig in a poke'?

stable	mud pit
bag	state of difficulty

Test your knowledge - and maybe learn something along the way.

TAKE THE QUIZ

A daily challenge for crossword fanatics.

TAKE THE QUIZ

WORDS AT PLAY

“In Vino Veritas” and Other Latin Phrases to Live By

- Top 10 Latin Phrases

10 of Our Favourite British Words and Slang

- Some of our favourite British words

Triumph, Ovation, and Other Words from Ancient Rome

- You'll love to hate these other words!

Until, Till, 'Til, or 'Till?

- 'Till' is actually older than 'until'

ASK THE EDITORS

'Everyday' vs. 'Every Day'

- A simple trick to keep them separate

What Is 'Semantic Bleaching'?

- How 'literally' can mean "figuratively"

Literally

- How to use a word that (literally) drives some pe...

Is Singular 'They' a Better Choice?

- The awkward case of 'his or her'

WORD GAMES

Name that Color!

- Can you tell chartreuse from vermilion?

TAKE THE QUIZ ›

EXHIBIT B

SINCE 1828

sen

noun (1)
Save Word

To save this word, you'll need to log in.

Log In
\ ˈsen \
plural sen

Definition of *sen*

(Entry 1 of 5)

a traditional monetary subunit of the yen — see *yen* at Money Table

sen

noun (2)
plural sen

Definition of *sen* (Entry 2 of 5)

a monetary subunit of the dollar (Brunei), ringgit, and rupiah — see *dollar, ringgit, rupiah* at Money Table

sen

noun (3)
plural sen

Definition of *sen* (Entry 3 of 5)

a monetary subunit of the riel — see *riel* at Money Table

sen

abbreviation

Definition of *sen* (Entry 4 of 5)

1 senate; senator
2 senior

Sen

biographical name
\ ˈsen \

Definition of *Sen* (Entry 5 of 5)

Amartya Kumar 1933– British (Indian-born) economist

First Known Use of *sen*

Noun (1)

1875, in the meaning defined above

Noun (2)

1952, in the meaning defined above

Noun (3)

1964, in the meaning defined above

History and Etymology for *sen*

Noun (1)

Japanese

Noun (2)

Malay, probably from English *cent*

Noun (3)

Khmer *sein*, probably from French *century*, abbreviation of *centime* centime

Learn More About *sen*

Share *sen*

Post the Definition of sen to Facebook Share the Definition of sen on Twitter

Time Traveler for *sen*

The first known use of *sen* was in 1875

See more words from the same year

Dictionary Entries Near *sen*

semy

sen

Sen

See More Nearby Entries

Statistics for *sen*

Look-up Popularity

Top 8% of words

Cite this Entry

“Sen.” *Merriam-Webster.com Dictionary*, Merriam-Webster, https://www.merriam-webster.com/dictionary/sen. Accessed 21 Feb. 2022.

Style: MLA
MLA Chicago APA Merriam-Webster
Seen & Heard
People are talking about

More Definitions for *sen*

Sen.

abbreviation

Kids Definition of *Sen.*

senate, senator

Test Your Vocabulary

Farm Idioms Quiz

- What does 'poke' refer to in the expression 'pig in a poke'?

mud pit | state of difficulty

stable | bag

“In Vino Veritas” and Other Latin Phrases to Live By

- Top 10 Latin Phrases

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- The awkward case of 'his or her'

WORD GAMES

Name that Color!

Can you tell chartreuse from vermilion?

- TAKE THE QUIZ ›

Forms of Government

How do people take and hold power?

- TAKE THE QUIZ ›

EXHIBIT C

Generated on: This page was generated by TSDR on 2022-02-21 11:25:30 EST

Mark: IVIEW

iView

US Serial Number: 87819937

Application Filing Date: Mar. 05, 2018

Filed as TEAS RF: Yes

Currently TEAS RF: Yes

Register: Principal

Mark Type: Trademark, Service Mark

TM5 Common Status Descriptor:

LIVE/APPLICATION/Under Examination

The trademark application has been accepted by the Office (has met the minimum filing requirements) and that this application has been assigned to an examiner.

Status: A fourth request for extension of time to file a Statement of Use has been granted.

Status Date: Oct. 04, 2021

Publication Date: Apr. 16, 2019 **Notice of Allowance Date:** Oct. 08, 2019

Mark Information

Mark Literal Elements: IVIEW

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Goods and Services

Note:
The following symbols indicate that theÂ registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Medical diagnostic reagents and assays for testing of body fluids

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(b)

For: Medical apparatus and instruments for diagnostic use, namely, apparatus for medical diagnostic testing in the fields of cancer or other tissue-based diagnostic testing, cytology and cell-based testing; Medical devices for obtaining body fluids samples; Medical diagnostic instruments for the analysis of body fluids; Medical diagnostic apparatus for testing cells and biomolecules

International Class(es): 010 - Primary Class

U.S Class(es): 026, 039, 044

Class Status: ACTIVE

Basis: 1(b)

For: Medical assistance; Medical consultations; Medical counseling; Medical information; Medical services, namely, in the fields of tissue based cytology and cell based testing, the analysis of body fluids and biomolecules, such as proteins, small molecules, cells, and nucleic acids, the detection and identification of nucleic acids in a sample, and the testing of health conditions, diseases, or abnormalities; all of the aforementioned not including provision of ophthalmic medical information

International 044 - Primary Class

U.S Class(es): 100, 101

Class(es):

Class Status: ACTIVE

Basis: 1(b)

Basis Information (Case Level)

Filed Use: No

Currently Use: No

Filed ITU: Yes

Currently ITU: Yes

Filed 44D: No

Currently 44E: No

Filed 44E: No

Currently 66A: No

Filed 66A: No

Currently No Basis: No

Filed No Basis: No

Current Owner(s) Information

Owner Name: Essenlix Corporation

Owner Address: 1 Deerpark Drive, Suite R
Monmouth Junction, NEW JERSEY UNITED STATES 08825

Legal Entity Type: CORPORATION

State or Country Where Organized: DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Julian D. Gonzalez

Docket Number: ESX-T043

Attorney Primary Email Address: julian@goldsteinpc.com

Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: Julian D. Gonzalez
1 DEERPARK DRIVE, SUITE R
MONMOUTH JUNCTION, NEW JERSEY UNITED STATES 08825

Phone: 732-274-1020

Correspondent e-mail: julian@goldsteinpc.com esxip@essenlix.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Oct. 06, 2021	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 04, 2021	EXTENSION 4 GRANTED	98765
Oct. 04, 2021	EXTENSION 4 FILED	98765
Oct. 04, 2021	TEAS EXTENSION RECEIVED	
Apr. 02, 2021	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Mar. 31, 2021	EXTENSION 3 GRANTED	98765
Mar. 31, 2021	EXTENSION 3 FILED	98765
Mar. 31, 2021	TEAS EXTENSION RECEIVED	
Oct. 01, 2020	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Sep. 29, 2020	EXTENSION 2 GRANTED	98765
Sep. 29, 2020	EXTENSION 2 FILED	98765
Sep. 29, 2020	TEAS EXTENSION RECEIVED	
Sep. 01, 2020	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Aug. 31, 2020	EXTENSION 1 GRANTED	76538
Apr. 08, 2020	EXTENSION 1 FILED	76538
Aug. 31, 2020	CASE ASSIGNED TO INTENT TO USE PARALEGAL	76538
Jul. 10, 2020	NOTICE OF REVIVAL - E-MAILED	
Jul. 09, 2020	EXTENSION RECEIVED WITH TEAS PETITION	

Jul. 09, 2020	PETITION TO REVIVE-GRANTED	88889
Jul. 09, 2020	TEAS PETITION TO REVIVE RECEIVED	
Jun. 08, 2020	ABANDONMENT NOTICE E-MAILED - NO USE STATEMENT FILED	
Jun. 08, 2020	ABANDONMENT - NO USE STATEMENT FILED	99999
Oct. 08, 2019	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Aug. 25, 2019	EXTENSION OF TIME TO OPPOSE PROCESS - TERMINATED	
Apr. 24, 2019	EXTENSION OF TIME TO OPPOSE RECEIVED	
Apr. 16, 2019	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Apr. 16, 2019	PUBLISHED FOR OPPOSITION	
Mar. 27, 2019	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Feb. 19, 2019	APPROVED FOR PUB - PRINCIPAL REGISTER	
Oct. 24, 2018	NOTIFICATION OF LETTER OF SUSPENSION E-MAILED	6332
Oct. 24, 2018	LETTER OF SUSPENSION E-MAILED	6332
Oct. 24, 2018	SUSPENSION LETTER WRITTEN	74306
Oct. 24, 2018	EXAMINER'S AMENDMENT ENTERED	88888
Oct. 24, 2018	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Oct. 24, 2018	EXAMINERS AMENDMENT E-MAILED	6328
Oct. 24, 2018	EXAMINERS AMENDMENT -WRITTEN	74306
Oct. 04, 2018	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Oct. 03, 2018	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Oct. 03, 2018	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jun. 22, 2018	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Jun. 22, 2018	NON-FINAL ACTION E-MAILED	6325
Jun. 22, 2018	NON-FINAL ACTION WRITTEN	74306
Jun. 18, 2018	ASSIGNED TO EXAMINER	74306
Mar. 19, 2018	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Mar. 19, 2018	TEAS AMENDMENT ENTERED BEFORE ATTORNEY ASSIGNED	88889
Mar. 19, 2018	TEAS VOLUNTARY AMENDMENT RECEIVED	
Mar. 10, 2018	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Mar. 08, 2018	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney: SONNEBORN, TRICIA L

Law Office Assigned: LAW OFFICE 110

File Location

Current Location: INTENT TO USE SECTION

Date in Location: Aug. 31, 2020

Proceedings

Summary

Number of Proceedings: 1

Type of Proceeding: Extension of Time

Proceeding Number: 87819937

Filing Date: Apr 24, 2019

Status: Terminated

Status Date: Aug 25, 2019

Interlocutory Attorney:

Defendant

Name: Essenlix Corporation

Correspondent Address: JULIAN D. GONZALEZ
1 DEERPARK DRIVE, SUITE R
MONMOUTH JUNCTION NJ , 08825

Correspondent e- esxip@essenlix.com , julian_gonzalez@essenlix.com

mail:

Associated marks

Mark	Application Status	Serial Number	Registration Number
IVIEW	Fourth Extension - Granted	87819937	

Potential Opposer(s)

Name: Roche Diagnostics GmbH

Correspondent Address: BRENT A. HARRIS
ROCHE DIAGNOSTICS OPERATIONS, INC.
9115 HAGUE ROAD
INDIANAPOLIS IN UNITED STATES , 46250

Correspondent e-mail: indianapolis.trademarks@roche.com

Name: Intersurgical Limited

Correspondent Address: TIMOTHY H. HIEBERT
SAMUELS & HIEBERT LLC
TWO INTERNATIONAL PLACE, SUITE 2330
BOSTON MA UNITED STATES , 02110-4104

Correspondent e-mail: hiebert@samuelsTM.com

Name: Roche Diagnostics Operations, Inc.

Correspondent Address: BRENT A. HARRIS
ROCHE DIAGNOSTICS OPERATIONS, INC.
9115 HAGUE ROAD
INDIANAPOLIS IN UNITED STATES , 46250

Correspondent e-mail: indianapolis.trademarks@roche.com

Name: Roche Diagnostics Operations, Inc.

Correspondent Address: BRENT A. HARRIS
ROCHE DIAGNOSTICS OPERATIONS, INC.
9115 HAGUE ROAD
INDIANAPOLIS IN UNITED STATES , 46250

Correspondent e-mail: indianapolis.trademarks@roche.com

Prosecution History

Entry Number	History Text	Date	Due Date
10	EXT GRANTED	Jun 14, 2019	
9	ADD'L 60-DAY REQUEST TO EXT TIME TO OPPOSE	Jun 14, 2019	
8	EXT GRANTED	May 17, 2019	
7	FIRST 90-DAY REQUEST TO EXT TIME TO OPPOSE	May 17, 2019	
6	EXT GRANTED	May 16, 2019	
5	FIRST 90-DAY REQUEST TO EXT TIME TO OPPOSE	May 16, 2019	
4	EXT GRANTED	May 16, 2019	
3	FIRST 90-DAY REQUEST TO EXT TIME TO OPPOSE	May 16, 2019	
2	EXT GRANTED	Apr 24, 2019	
1	FIRST 30-DAY REQUEST TO EXT TIME TO OPPOSE	Apr 24, 2019	

EXHIBIT D

About i-SENS, Inc.

Founded in year 2000, i-SENS is a global company dedicated to improving the lives of people with diabetes and those who care for them.

CareSens® is a recognized worldwide brand that provides fast and highly accurate blood glucose test results. With

an annual production capacity of 2.1 billion test strips from highly efficient manufacturing facilities (two in Korea, one in China), i-SENS exports to over 110 countries including the USA, Japan, and Europe.

Working closely with many healthcare professionals, i-SENS also supplies convenient POCT devices (HbA1c, Blood Gas, Electrolyte, PT/INR Analyzer) as well as Immunoassay Analyzer and CGMS which are launching in the near future.

EXHIBIT E

Product Overview

Blood Glucose Monitoring

Point of Care

Veterinary Care

Accessories

Diabetes Management Service

CareSens® Blood Glucose Monitoring Systems

The CareSens® family of products helps you incorporate blood glucose testing into your daily lives by delivering fast, highly accurate results.

i-SENS launched 'CareSens®' Blood Glucose Monitoring System in 2003 with the world's first technology which measures blood glucose level using 0.5 μL blood sample within 5 seconds. Since then, i-SENS has strengthened its CareSens® brand by continuously developing and launching CareSens® series with its advanced technology.

i-SENS BGMS continues to meet the stringent quality requirements of international standards. CareSens® S Fit was recently cleared by the FDA. It complies with ISO 15197:2013/EN ISO 15197:2015 international standard and new FDA standards.

Compare CareSens® meters

	CareSens® N	CareSens® N Premier	CareSens® Dual	Ca
	 "Millions of customers' choice"	 "Convenient with Bluetooth®"	 "Blood glucose & β-ketone measurement"	"E ar
Enzyme	GOD	GOD	GDH-FAD	
Sample Type	Fresh capillary whole blood	Fresh capillary whole blood	Fresh capillary / Venous / Neonatal / Arterial whole blood	Ve Ar
Sample Size	0.5 µL	0.5 µL	Blood glucose: 0.4 µL Blood β-ketone: 0.5 µL	
Backlight		✔	✔	
Strip ejection button		✔	✔	
Memory	1,000	1,000	1,000	
Battery Life (tests)	3,000	3,000	1,000	

Communication	USB	USB, Bluetooth® (Option)	USB, Bluetooth®

EXHIBIT F

ivisen™ IA-1100

Fluorimetric Immunoassay Analyzer

Specifications

Operating Parameters

Target
IgM/IgG Combo, IgG Single

Assay Method
Sandwich Immunoassay

Result
Positive, Negative

Sample Type
Capillary, Venous Blood
(Whole Blood, Plasma, Serum)

Sample Volume
< 25 µL

Analysis Time
15 min (IgM/IgG, IgG)

Display
7 inch LCD touch screen

Printer
2 inch thermal printer (built-in)

Dimensions / Weight
162(W) x 407(H) x 360(D) mm /
6.5 kg (accessories excluded)

Power
AC 100~240 V, 50/60 Hz, 1.3 A

System Connectivity
2 USB sockets, Serial,
LAN / LIS

Clinical Performance

IgM/IgG

IgM/IgG Combo		RT-PCR assay		
		Positive	Negative	Total
ivisen IA, COVID-19 Ab (IgM/IgG)	Positive	58	9	67
	Negative	2	194	196
	Total	60	203	263

PPA/Sensitivity: 96.7 % (95 % CI: 88.6 %~99.1 %)
NPA/Specificity: 95.6 % (95 % CI: 91.8 %~97.7 %)

IgG

IgG Single		RT-PCR assay		
		Positive	Negative	Total
ivisen IA, COVID-19 Ab (IgG)	Positive	58	6	64
	Negative	2	197	199
	Total	60	203	263

PPA/Sensitivity: 96.7 % (95 % CI: 88.6 %~99.1 %)
NPA/Specificity: 97.0 % (95 % CI: 93.7 %~98.6 %)

The sensitivity for IgM/IgG & IgG over time

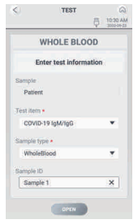
Days post PCR confirmation	N	Sensitivity
≤7	36 (60 %)	89 %
8-14	18 (30 %)	94 %
≥15	6 (10 %)	100 %

The cross-reactivity of IgM/IgG & IgG

Clinical sample	# (Neg./Pos.)	Clinical sample	# (Neg./Pos.)	Clinical sample	# (Neg./Pos.)
NL63	3 (3/0)	SARS-CoV-1	3 (3/0)	HCV	3 (3/0)
229E	3 (3/0)	Influenza A	3 (3/0)	HBV	3 (3/0)
OC43	3 (3/0)	Influenza B	3 (3/0)	HIV	3 (3/0)
HKU1	3 (3/0)	RSV	3 (3/0)		
MERS	3 (3/0)	ANA	3 (3/0)		

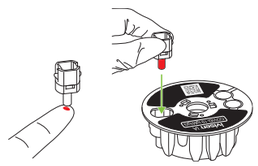
Test Procedure

1. Enter test information



*Enter the sample ID using barcode scanner or touch-screen keyboard

2. Collect specimen and assemble sample collector



Capillary blood sampling

Sample collector assembly

3. Insert the cartridge and tip

Cartridge insertion

4. Start a test

5. Check the test results

AD188 REV0 11/2020

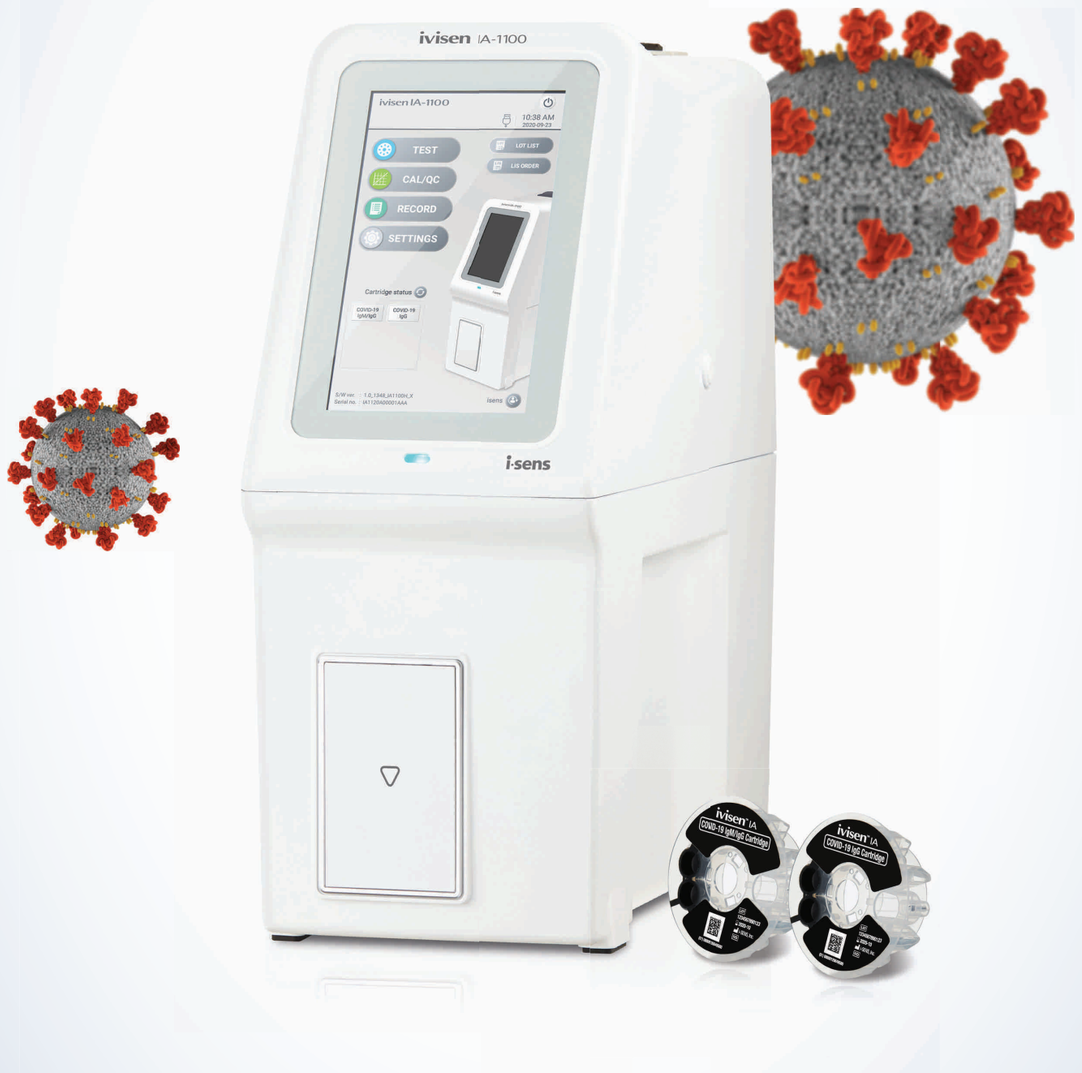
i-SENS, Inc. 43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea
Tel: +82-2-916-6191 www.i-sens.com

FOLLOW US ON

Sensing Ahead, Caring More

ivisen™ IA-1100

Fluorimetric Immunoassay Analyzer



COVID-19 **IgM/IgG**

COVID-19 **IgG**

Sensing Ahead, Caring More

ivisen™ IA-1100

Fluorimetric Immunoassay Analyzer

Maintenance Free

- All-in-one cartridge contains all reagents
- Constant temperature control & automated pipetting

Fast, Safe & Reliable Results

- Small sample volume (25 µL)
- Fast test results (<15 minutes)
- Highly sensitive TRF (Time-Resolved Fluorescence) applied
- Various sample types available
  (Arterial and capillary whole blood, plasma, serum)
- No hematocrit bias due to centrifugation

Easy to Use & Simple Operation

- User friendly interface
- Provides 7-inch capacitive touch color LCD
- Convenient sample collecting

Connectivity Management

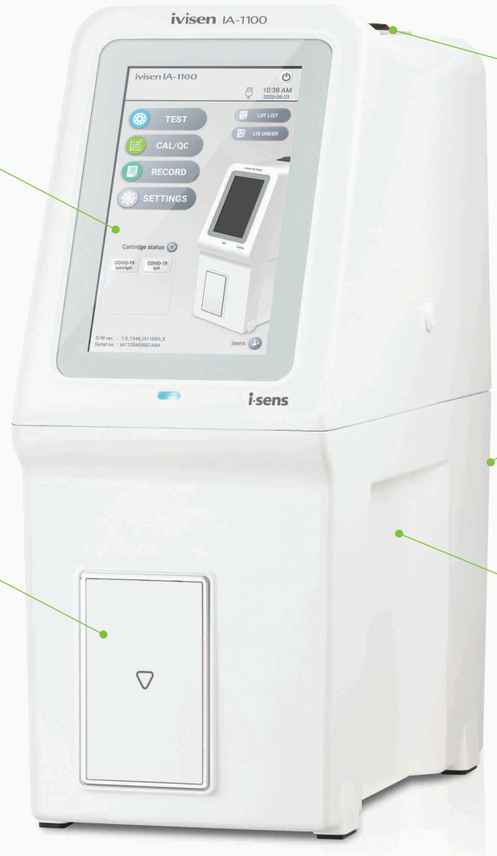
- LIS /HIS bidirectional communication
- External battery
- Internal printer
- Data backup using USB drive

Efficiency

- Able to detect both IgM and IgG at the same time (2-in-1 cartridge)
- Compact, fully automated POCT analyzer
- Battery-powered for use in resource-limited enviroment
- Easy to expand with additional infectious diseases

Intuitive Touch Screen Interface

Automated Cartridge Module

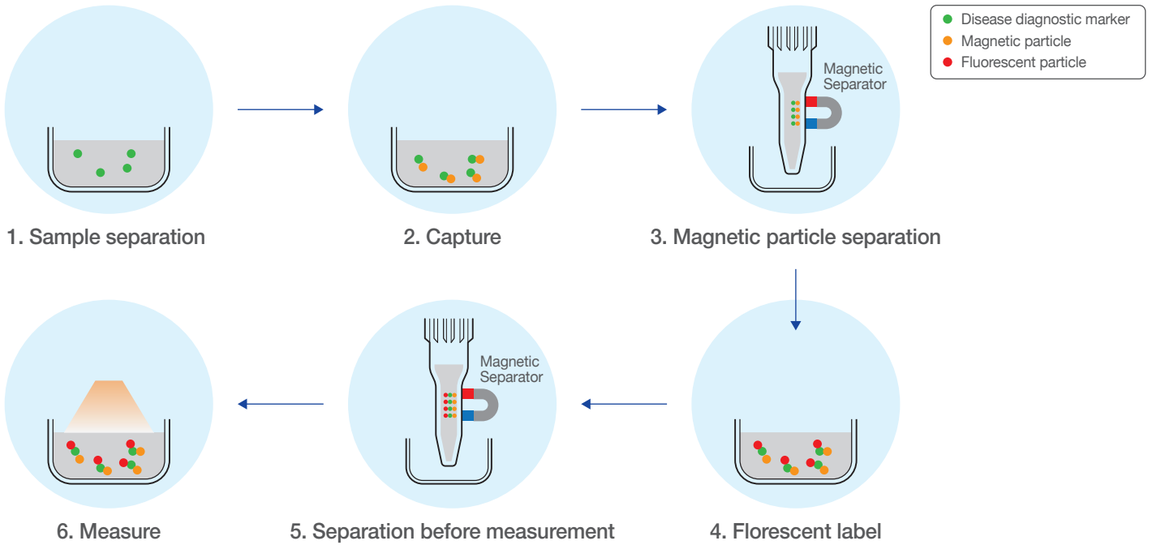


Built-In Printer

External Input / Output Ports

Grip Curved & Ergonomical Design

TRF Measurement System



COVID-19 Cartridge

- Storage temperature: 1-30 °C
- Shelf life: 12 months

IgM/IgG

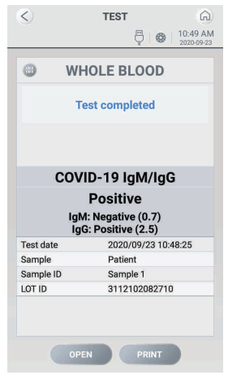
1 Box/ 40 Tests

IgG

1 Box/ 40 Tests

Test Result

- Large visual touchscreen results display
- The results can be printed on paper through the built-in printer



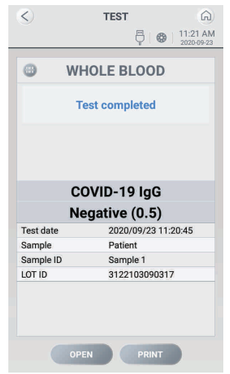


EXHIBIT G

PerkinElmer
For the Better

Search Results for 'ivisense'

Products & Services (36)

Resource Library (141)

FEATURED CATEGORIES

Applications (26)
Products (36)
Solutions (19)

FILTER BY Expand All | Collapse All

Application −
- [ ] In vivo imaging (1)

Fluorescent Agent Type +

Imaging Modality +

Product Brand Name +

Therapeutic Area +

Type +

Sort by Best Match

1-25 of 36 Products & Services

IVISense 680 Fluorescent Cell Labeling Dyes (VivoTrack)

Price Range : 138.00 USD - 347.00 USD

NEV12000 , NEV12001

Label and track mammalian cells including stem cells, T-cells, macrophages and more with IVISense™ 680 flu...

IVISense Vascular Fluorescent Probes (AngioSense)

Price Range : 716.00 USD - 717.00 USD

NEV10054EX , NEV10011EX

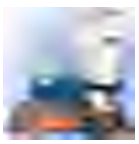
In vivo optical imaging of vascular changes and vascular leak is an emerging modality for studying altered...

IVISense Pan Cathepsin Fluorescent Probes (ProSense)

Price Range : 717.00 USD - 847.00 USD

NEV10003 , NEV10001EX , NEV11171

Proteases perform a fundamental role in protein regulation. Altered activity of lysosomal cathepsins, a cl...



IVISense Fluorescent Dyes (VivoTag)

Price Range : 212.00 USD - 830.00 USD

NEV11118 , NEV11173 , NEV11174 , NEV11119 , NEV11120 , NEV11107 , NEV11108 , NEV11273 , NEV11274 , NEV11219 , NEV11220 , NEV10121 , NEV10122 , NEV10123 , NEV10124 , NEV11223 , NEV11224

Label antibodies, small molecules, proteins, or peptides with IVISense NIR fluorescent dyes. PerkinElm...

IVISense Bacterial 750 Fluorescent Probe - RediJect Soltuion

Price Range : 186.00 USD - 596.00 USD

133397 , 133398 , 133399

IVISense™ Bacterial 750 (XenoLight™ Rediject™ Bacterial Detection) fluorescent probe is a near-infrared (N...

IVISense 2-DG 750 Fluorescent Probes - RediJect Solution (XenoLight)

List Price : 622.00 USD

760562

IVISense™ 2-DeoxyGlucosone (DG) (XenoLight™ 2-DG) fluorescent imaging probes in RediJect™ Solution enable ...

IVISense Osteo Fluorescent Probes (OsteoSense)

Price Range : 724.00 USD - 725.00 USD

NEV10020EX , NEV10053EX , NEV11105

Image and quantify osteoporosis, arthritis, cancer metastases, and other bone diseases, as well as normal ...

IVISense DiR 750 Fluorescent Cell Labeling Dye (XenoLight)

List Price : 220.00 USD

125964

IVISense™ DiR 750 (XenoLight™ DiR) NIR fluorescent dye can be used for non-invasive imaging of T-cell or s...

IVISense Gastrointestinal 750 Fluorescent Probe (GastroSense)

List Price : 716.00 USD

NEV11121

IVISense™ Gastrointestinal 750 (GastroSense™ 750) is a near-infrared, fluorescently-labeled macromolecule ...

IVISense Bombesin Receptor 680 Fluorescent Probe (BombesinRSense)

List Price : 752.00 USD

NEV10090

IVISense™ Bombesin Receptor 680 (BombesinRSense™ 680) is a targeted NIR fluorescent probe for in vivo imag...

IVISense Neutrophil Elastase 680 FAST

List Price : 847.00 USD

Fluorescent Probe

NEV11169

Neutrophil Elastase (NE) is a protease secreted by neutrophils. Neutrophils are the first responders of th...

IVISense Oncology Fluorescent Imaging Panel

List Price : 2208.00 USD

NEV20005

Maximize your in vivo imaging preclinical cancer research with our IVISense™ Oncology Fluorescent Imaging ...

IVISense Tumor Metabolism Fluorescent Imaging Panel

List Price : 4435.00 USD

NEV20015

Advance your understanding of cancer using IVISense™ Tumor Metabolism Fluorescent Imaging Panel specific f...

IVISense Cat B FAST Fluorescent Probes

Price Range : 888.00 USD - 914.00 USD

NEV11112 , NEV11098

IVISense™ Cat B FAST fluroescent probes enable non-invasive in vivo detection of disease status and progre...

IVISense 2-DG 750 Fluorescent Probes - RediJect Solution (XenoLight)

List Price : 191.00 USD

760567

IVISense™ 2-DeoxyGlucosone (DG) (XenoLight™ 2-DG) fluorescent imaging probes in RediJect™ Solution enable ...

IVISense GFR 680 Fluorescent Probe (GFR-Vivo)

List Price : 542.00 USD

NEV30000

IVISense™ GFR 680 (GFR-Vivo™) is a NIR fluorescent inulin based probe that enables quantitative assessment...

IVISense Sample Pack Fluorescent Imaging Panel

List Price : 671.00 USD

NEV20000

Not sure what reagents or probes work best for your in vivo imaging research studies?

Try our IVISense™ Sa...

IVISense Hypoxia CA IX 680 Fluorescent Probe (HypoxySense)

List Price : 738.00 USD

NEV11070

IVISense™ Hypoxia CA IX 680 (HypoxiSense™ 680) is a carbonic anhydrase IX (CA IX) targeted fluorescent in ...

IVISense Folate Receptor 680 Fluorescent Probe (FolateRSense 680)

List Price : 745.00 USD

NEV10040

IVISense™ Folate Receptor 680 fluorescence imaging probe (FolateRSense™) is highly specific and sensitive ...

IVISense Integrin Receptor Fluorescent Probes (IntegriSense)

Price Range : 855.00 USD - 871.00 USD

NEV10640 , NEV10645 , NEV10873

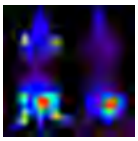
Integrins are a superfamily of transmembrane cell surface receptors that mediate signal transduction, cell...

IVISense Acute Vascular Fluorescent Probes (Genhance)

Price Range : 214.00 USD - 815.00 USD

NEV10117 , NEV10130 , NEV10118 , NEV10177

IVISense™ Acute Vascular (Genhance™) fluorescent probes enable imaging and quantitation of acute vascular ...



IVISense Arthritis Fluorescent Imaging Panel

List Price : 2922.00 USD

NEV20003

Detect molecular players in arthritis pathology in vivo with PerkinElmer's IVISense™ Arthritis Fluorescent...

IVISense Transferrin Receptor 750 Fluorescent Probe (Transferrin-Vivo)

List Price : 752.00 USD

NEV10091

Transferrin is an important serum protein that mediates iron transport into cells via the transferrin rece...

IVISense 2-DG 750 Fluorescent Probes - RediJect Solution (XenoLight)

List Price : 195.00 USD

760561

IVISense™ 2-DeoxyGlucosone (DG) (XenoLight™ 2-DG) fluorescent imaging probes in RediJect™ Solution enable ...

IVISense Cat K 680 FAST Fluorescent Probe

List Price : 872.00 USD

NEV11000

IVISense™ Cat K 680 FAST NIR fluorescent probe enables monitoring and quantifying cathepsin K (Cat K) acti...

Back 1 2 Next

Jump to:

EXHIBIT H

Optical Imaging

Sensitivity to Image Down to a Single Cell

Whether your research involves better understanding molecular pathways of disease, tracking disease progression, or evaluating therapeutic effectiveness of drug candidates, your cutting-edge research commands high-sensitivity and reliable optical imaging data.

In vivo optical imaging is a fast, cost-efficient, easy-to-use, and powerful technique to help you non-invasively study molecular and biological processes of disease, or help drive discovery and development of novel drug candidates using bioluminescent or fluorescent reporters.

Bioluminescence and fluorescence imaging offer their own unique characteristics for small animal imaging. Bioluminescence imaging (BLI) uses luciferase genes and offers minimal background signals from the animal tissues, provides high specificity and precise quantification, and can be used to detect and monitor biological events such a tumor growth deep within the tissue. Fluorescence imaging (FLI) is ideal for monitoring and quantifying cell behavior of biological targets.

We are here to help you achieve your research goals with our leading IVIS® and FMT® molecular imaging platforms and diverse range of optical reagents. From single mode 2D optical and 3D tomography to multimode integrated systems, we have the tools you need to help you get the answers you are searching for.

Bioluminescence | Fluorescence | Optical Reagents | Image Gallery

Bioluminescence

Exquisitely sensitive, cost-effective, easy-to-use

That's what's behind our bioluminescence imaging systems.

Superior signal to noise ratio, high sensitivity, short acquisition times and ease-of-use make bioluminescence imaging an excellent non-invasive tool to better understand the mechanisms of disease biology. Accelerate your *in vivo* imaging research studies or propel your drug discovery development process using IVIS®, the most widely published bioluminescence imaging platform in the industry.

IVIS® Lumina X5 Imaging System

IVIS® Lumina S5 Imaging System

IVIS® Lumina III In Vivo Imaging System

IVIS Lumina XRMS In Vivo Imaging System

IVIS® Lumina LT In Vivo Imaging System

IVIS Spectrum In Vivo Imaging System

IVIS® SpectrumCT In Vivo Imaging System

IVIS® SpectrumBL High-Throughput In Vivo Optical Imaging System

Living Image Software

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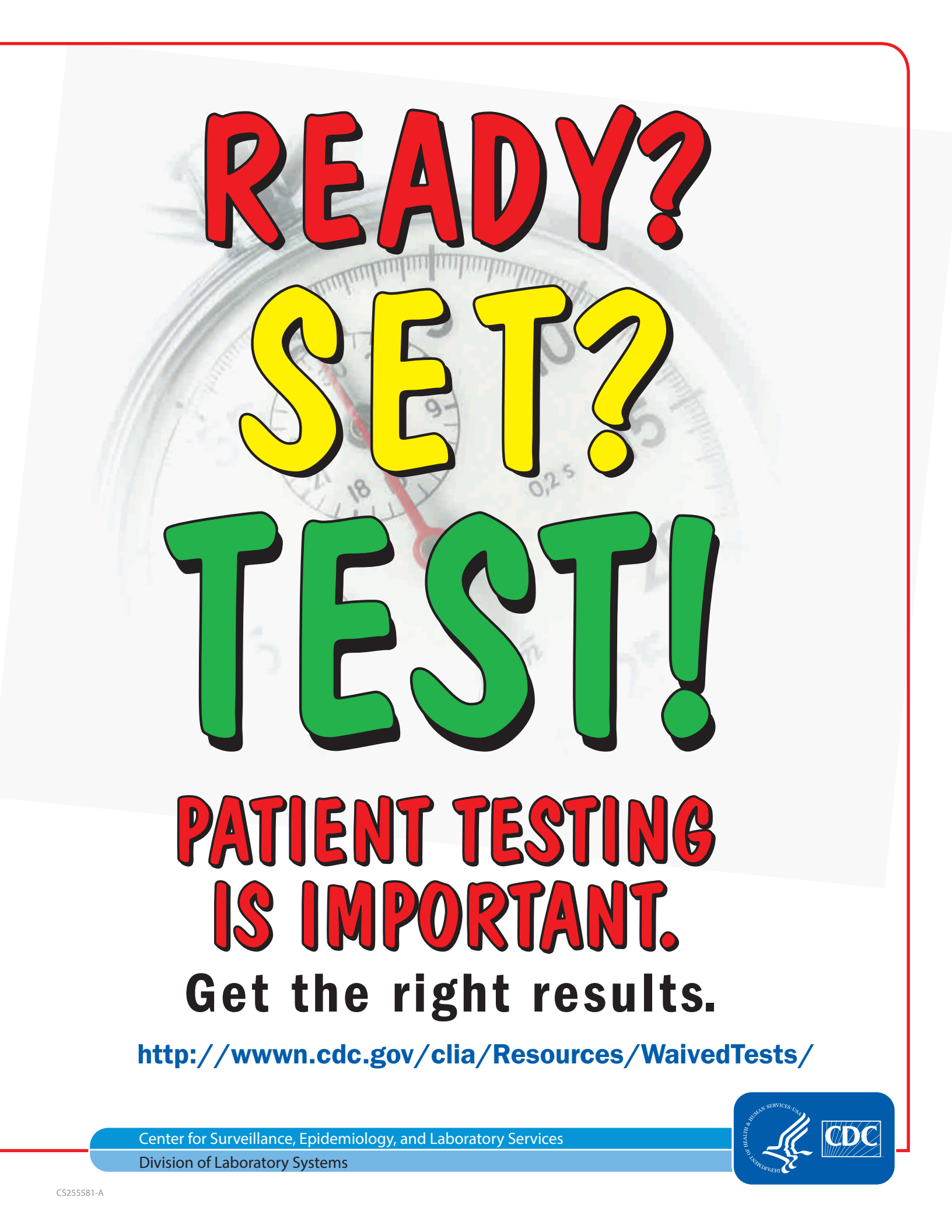
EXHIBIT I


READY?
SET?
TEST!
PATIENT TESTING
IS IMPORTANT.
Get the right results.
http://wwwn.cdc.gov/clia/Resources/WaivedTests/
Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems
CDC
CS255581-A

Introduction

Background

Health care providers use test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these tests are called waived tests and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria. The FDA list of waived tests is continuously being revised as new tests are waived. The most current information on FDA cleared waived tests can be found at the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Purpose

CLIA requires that waived tests must be simple and have a low risk for an incorrect result. However, this does not mean waived tests are completely error-proof. To decrease the likelihood of incorrect results, waived testing needs to be performed correctly, by trained personnel and in an environment where good testing practices are followed.

Although not routinely done, the Centers for Medicare & Medicaid Services (CMS) will inspect waived testing sites under certain circumstances such as:

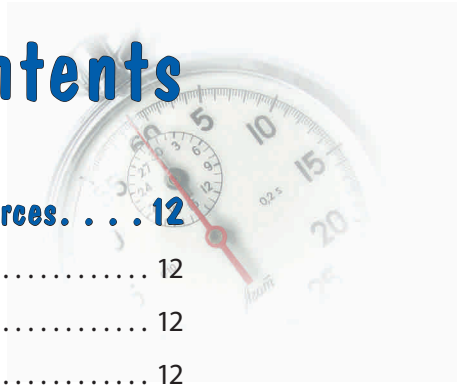
- if a complaint is made,
- to determine if the testing site is performing tests not permitted with a certificate of waiver,
- if there is risk of harm to a patient due to inaccurate testing, and
- to collect information about waived tests.

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

The CLIA requirements for testing under a Certificate of Waiver can be found here: http://wwwn.cdc.gov/clia/Regulatory/default.aspx

Although some of the recommendations in this booklet exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high quality test results and will enhance patient safety.

Contents



READY?

Overview

Certain steps need to be taken even before a test is begun to be sure results are accurate. Most importantly, follow the manufacturer's instructions throughout the testing process. Problems found in testing sites that perform waived tests are most often the result of not following this critical step.

Prepare for Testing

Testing should be performed in an area with adequate space to safely conduct testing while maintaining patient privacy. Testing and storage areas should be monitored to be sure they meet specific environmental requirements described in the manufacturer's instructions. Equipment used for testing should be maintained and calibration checks should be performed as directed in the manufacturer's instructions. Some important points to consider are:

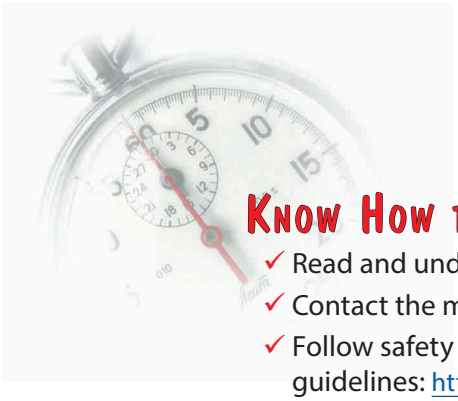
- ✓ Clean work surfaces before and after testing.
- ✓ Perform testing in a well lit area.
- ✓ Check and record temperatures of the testing and reagent storage areas. See Appendix A for examples of daily temperature logs.
- ✓ Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- ✓ Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- ✓ Check that all kit reagents came from the same kit lot. Do not mix reagents.
- ✓ Inspect reagents for damage, discoloration, or contamination, and discard if found.
- ✓ Prepare reagents according to manufacturer's instructions.
- ✓ Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- ✓ Inspect equipment and electrical connections to be sure they are working.
- ✓ Perform equipment calibration checks, as needed, following the manufacturer's instructions.

The Test Instructions

Testing sites that perform testing under a CLIA Certificate of Waiver must follow the current manufacturer's test instructions. See Appendix B for an explanation of the common components found in a manufacturer's instructions. Keep in mind that manufacturer's instructions may be updated or changed and instructions from different manufacturers for the same type of testing, such as glucose, may not be the same. The following steps should be taken to be sure the current test instructions are being followed:

- ✓ Keep a copy of the manufacturer's instructions on hand for easy reference.
- ✓ Check the manufacturer's instructions with each new lot and shipment of test kits to make sure there are no changes from the test kits being used.
- ✓ File the old manufacturer's instructions and replace with the new copy if there are changes.
- ✓ Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.

Some manufacturers provide quick reference instructions that can be posted in the testing area. If manufacturer's instructions are updated, the quick reference instructions may need to be updated as well. If your testing site has a procedure manual, the site specific procedure will need to be updated.



Know How to Do the Test the Right Way

- ✓ Read and understand the manufacturer's instructions and/or site specific procedure.
- ✓ Contact the manufacturer if there is any information that is not clear.
- ✓ Follow safety precautions including Occupational Safety and Health Administration (OSHA) guidelines: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
- ✓ Practice all tests, while an experienced person watches, before testing patient samples and reporting patient results.
- ✓ Document training on all tests in staff personnel files.

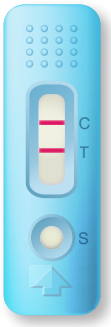
"Off-Label Use" of Waived Tests

Based on the testing site's need and the unique population it serves, there may be instances when the site chooses to modify an FDA-cleared or approved test system. Modification means using a test system in a way other than that described in the intended use, precautions, limitations, or other sections of the manufacturer's instructions (See Appendix B for an explanation of the common components found in a manufacturer's instructions). The modified use of a test system is considered "off-label use" because it is not supported by the manufacturer's clinical data and it is not part of the FDA-cleared or approved instructions. "Off-label use", or modified use of a test system, defaults the test to the high-complexity testing category under CLIA regulations, and will require sites using the modified test system to meet all applicable CLIA requirements for high-complexity testing. These include requirements for proficiency testing (PT), establishing performance characteristics, quality control (QC), quality assessment, and adherence to personnel qualifications. Laboratories with a CLIA Certificate of Waiver that are using modified test systems will need to upgrade to a CLIA Certificate of Compliance or a CLIA Certificate of Accreditation if they continue to use modified test systems.

Example of "Off-Label Use" of Waived Tests

Using a waived blood glucose monitoring system to test a patient whose hematocrit or oxygenation level is above or below the range indicated in the manufacturer's instructions would be an "off-label use" of this system. Results of blood glucose testing in this situation may lead to clinical interventions that could cause patient harm. If the patient's hematocrit and oxygenation level are within the manufacturer's stated limits, then performing a glucose test using the waived glucose monitoring system would not be considered off-label testing and the test system would still be considered waived.

Quality Control Testing

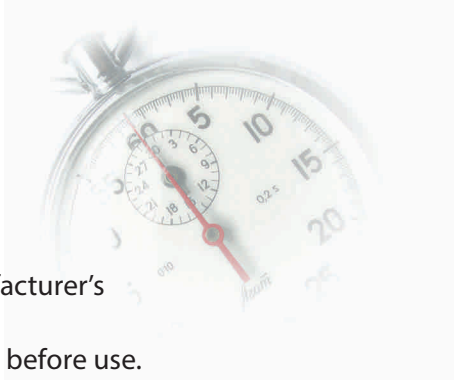


QC testing gives confidence that your results are accurate and reliable. The manufacturer's instructions or site specific procedure explain what the controls are checking, the steps for performing QC testing, and when to do QC testing. Incorrect QC results alert the user about potential problems such as reagent/test kit deterioration, equipment failure, environmental conditions, or human error.

What are the types of controls?

Two types of controls are generally found in waived tests:

- Internal controls (also referred to as built-in or procedural controls) evaluate whether:
  - the test is working as it should,
  - enough sample is added,
  - the sample is moving through the test strip correctly, and/or
  - the electronic functions of the instrument are working correctly.



- External controls evaluate whether:
  - the entire testing process is performed correctly, and
  - the control results are in the expected ranges or values as found in the manufacturer's instructions.

External controls are similar to patient samples but may need additional processing before use. Follow the manufacturer's instructions. External controls are not always included in the test kit and may need to be purchased separately.

How often should QC testing be done?

Each testing site should have a policy for QC testing. When deciding on a control testing schedule, consider the:

- manufacturer's instructions
- stability of the test (check expiration dates and storage requirements),
- environment (power outages or mechanical breakdowns of refrigerators can cause QC or testing material to go bad), and
- skills of the person performing the test (newly trained versus experienced).

Controls should be treated and tested in the same way as patient samples and by the same personnel who routinely perform patient testing. At a minimum, follow the manufacturer's instructions and test controls with:

- each new shipment of kits/reagents,
- a change in lot numbers, and
- each new operator.

Tracking of QC results

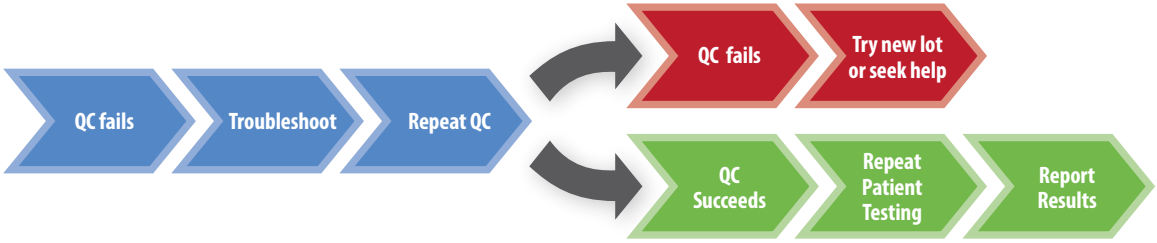
Documenting and tracking QC results can show whether a test is being performed correctly and if the test is working correctly. A periodic review of QC records can show whether the QC results are changing over time. This information can help identify problems that may be affecting patient testing and need to be addressed. See Appendix C for examples of QC logs and result logs.

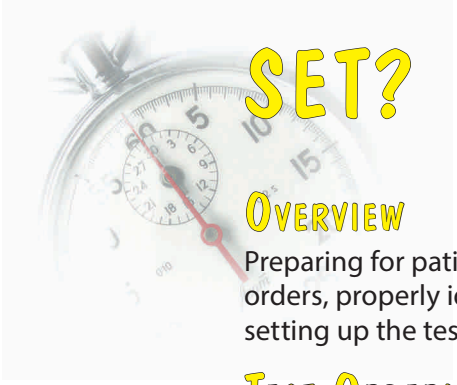
Actions for unexpected QC results

If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error such as outdated reagents or test devices.
- ✓ Check to see if reagents were stored correctly.
- ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
- ✓ For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.

Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final acceptable results.





Set?

Overview

Preparing for patient testing is as important as performing the test. Paying attention to test orders, properly identifying and preparing the patient, collecting a good quality sample, and setting up the test system and testing area all contribute to quality test results.

Test Ordering

Before collecting a sample, confirm:

- ✓ The test order — if there is a question whether the order is correct, check with the individual who requested the test.
- ✓ Patient identification — because names can be similar and lead to confusion, use birth dates, middle initials, identification numbers or other ways to make sure the sample is collected from the correct patient.

Patient Preparation

Consult with the patient regarding:

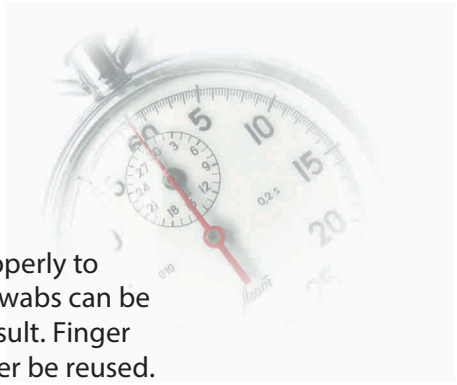
- ✓ Pretest instructions — some tests require preparation by the patient such as fasting for a glucose test. Verify these instructions were followed before collecting the sample.
- ✓ Pretest information — discuss factors such as medical indications, medications, or other interfering substances that can affect test results with the patient. This information can often be found in the *Limitations* section of the manufacturer's instructions.
- ✓ The test(s) — make sure the patient understands what the test(s) and result(s) will mean to their health.
- ✓ Patient counseling — some tests, such as HIV tests, benefit from counseling on what the test results will mean for the patient.

Sample Collection

Quality patient samples are critical for accurate and reliable test results. The person collecting the sample should have a good understanding of the type of sample needed for the test and how to collect it. The manufacturer's instructions have this information as well as directions for sample storage and handling. Do not test samples that are improperly collected or handled.

Caution: When a test is approved for both waived and non-waived testing, the manufacturer's instructions may include instructions that could be performed using more than one type of sample. Waived tests may only be performed using unprocessed samples. Examples of unprocessed samples include:

- whole blood (fingerstick or anticoagulated blood collected by venipuncture),
- urine,
- throat swab, nasopharyngeal swab, nasal wash or aspiration,
- stool,
- saliva, oral fluid, and
- gastric biopsy.



Collection Devices

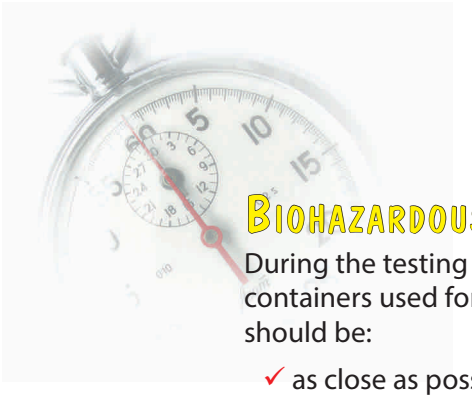
Collection devices are an important part of sample collection and must be used properly to obtain good results. Do not substitute swabs that come in a sample collection kit. Swabs can be made of different material and using the wrong swab may interfere with the test result. Finger stick and venipuncture collection devices are for one-time use only and should never be reused. Finger stick devices come in various sizes from pediatric to adult. Be sure to use the appropriately sized device for your patient. Some collection devices ensure the delivery of the correct sample volume and some contain additives that are needed for the test to work correctly. Therefore, it is important to follow the manufacturer's instructions when using sample collection devices.

Sample Labeling

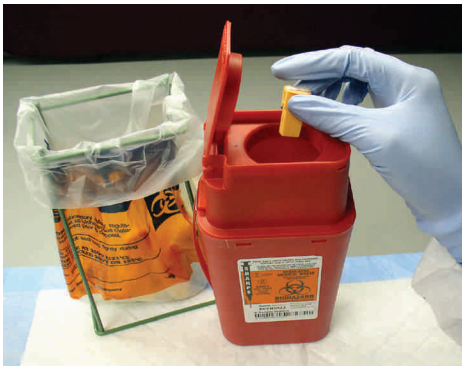
Be sure to label the sample as soon as it is collected with a unique identifier such as name and date of birth to prevent sample mix-up. Sample labels may also include the date and time of collection, and who collected the sample. For tests in which the sample is applied directly to the test device (for example: test strip or cassette), label the test device with the patient identifier before collecting the sample.

Safety Issues

- ✓ Follow OSHA safety guidelines for occupational exposure to bloodborne pathogens: http://www.osha.gov/SLTC/bloodbornepathogens/index.html and CDC's Exposure to Blood - What Health-Care Workers Need to Know: http://www.cdc.gov/hai/
- ✓ Wear appropriate personal protective equipment (PPE) such as gloves.
- ✓ Clean hands and change gloves between patients. See Appendix D for job aids on hand hygiene, exposure, and glove removal.
- ✓ Follow work practices that reduce the risk of exposure, including:
  - handle all blood and body fluids as if they are infectious,
  - use required PPE and safety devices,
  - do not eat, drink, or apply cosmetics in the testing area,
  - be cautious of exposure to mucous membranes such as eyes, nostrils, and mouth,
  - wear goggles or face shields,
  - avoid the use of needles and lancets if safe and effective alternatives are available,
  - never re-use single-use devices such as needles and lancets,
  - avoid recapping needles, transferring a body fluid between containers, and opening blood tubes,
  - dispose of used sharps properly in puncture-proof sharps containers,
  - report all occupational exposures promptly to ensure that you receive appropriate follow-up care,
  - report any real or potential hazards you observe to the person who directs or oversees testing,
  - participate in training related to infection prevention, and
  - get hepatitis B vaccination.



Biohazardous Waste



During the testing process, the biohazard bags and sharps containers used for disposal of contaminated materials should be:

- ✓ as close as possible to the immediate testing area,
- ✓ upright throughout use,
- ✓ replaced routinely, and
- ✓ not overfilled.

Containers for contaminated waste must be:

- ✓ constructed to contain all contents and prevent leakage of fluids during handling, storage, transport and/or shipping,
- ✓ labeled or color-coded to indicate biohazard material, and
- ✓ closed prior to removal to prevent spillage or protrusion of contents during handling.

Hazardous waste cannot be disposed of with regular trash. Use proper biohazard containers to dispose of waste and sharps. Each testing site should have site specific procedures that comply with local, state, and federal requirements for safe disposal of biohazardous waste generated from sample collection and testing. Local hospitals and/or clinics may be able to provide information about regulated waste disposal. Useful websites include:

- Federal website: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- State program site: http://www.osha.gov/dcsp/osp/index.html

Disinfecting Work Surfaces

- ✓ Disinfect surfaces before performing any test procedure, whenever contamination is visible, and before leaving the testing area. Bacteria and viruses can be present in very high concentrations in just a few drops of blood and some remain infectious for at least one week in dried blood on countertops and doorknobs.
- ✓ Use the appropriate disinfectant for decontaminating your work area. See Appendix E: Common Disinfectants and Antiseptics.

TEST!

Overview

Once the sample is collected, the testing phase begins. Test performance, result interpretation, recording, and reporting are activities involved in this phase.

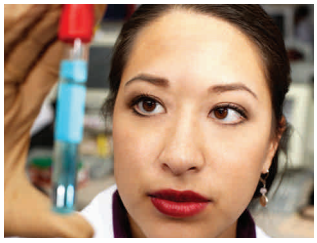
Performing the Test

When performing a test, some important points to remember are:

- ✓ Follow the testing steps in the exact order as they are in the manufacturer's instructions.
- ✓ Test QC following the manufacturer's instructions.
- ✓ Have the manufacturer's instructions, site specific procedure, or a quick reference guide at the testing area.
- ✓ Use timers and follow the required timing intervals before reading test results.
  - Reading the results too soon can cause invalid or false negative results due to incomplete reaction of the sample and reagents.
  - Reading a test after the time given in the manufacturer's instructions can lead to:
    - › false positive results – due to over development of color,
    - › false negative results – fading of the reaction or color, or
    - › invalid results – the reaction moves beyond a visible area.

Reading the Results

Interpret test results according to the manufacturer's instructions. Keep the quick reference guide or color charts available to help interpret results. Test results are either quantitative, qualitative, or a combination of the two with a number result that is interpreted into a non-numeric result.



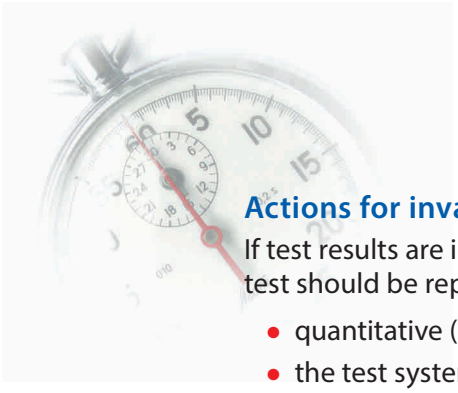
- ***Quantitative*** – number results produced by the test device or instrument. These results give the amount of substance being measured and are reported in specific measurement units.
- ***Qualitative*** – results are interpreted as positive, negative; reactive, non-reactive; or invalid. These results identify the presence or absence of a particular substance, condition, or microbial organism.

Resolving Problems

Problems that occur during the testing process or with equipment or material that are used during testing should be documented, reported to the person who directs or supervises the testing, and corrected. A few examples of problems include:

- improperly labeled samples,
- freezer or refrigerator failure,
- QC failure, and
- defective collection devices.

Trends can be identified by capturing and tracking this information and problems in the testing process can be identified as a result.



Actions for invalid or questionable test results

If test results are invalid, compromised, or disagree with the patient's clinical information, then the test should be repeated. Additionally, testing should be repeated when:

- quantitative (numerical) results have values beyond the measuring range of the instrument, or
- the test system gives an "invalid" result or prevents the display of the result.

The manufacturer's instructions for test performance should include steps for handling high or low results that cannot be accurately measured.

Test results should not be reported until the problem(s) are identified and corrected.

Recording Results

Record test results legibly in a log or following the testing site's policy and keep as a permanent record. These records should have enough detail for easy retrieval of information. Guidelines for recording results include:

- Quantitative (numerical) results should be recorded in the appropriate units of measurement.
- Qualitative results should be recorded using words or abbreviations rather than symbols. For example use:
  - "Positive" or "Pos", "Reactive" or "R" instead of "+", and
  - "Negative" or "Neg", "Nonreactive" or "NR" instead of "-".

Invalid or unacceptable results should also be recorded. If a test needs to be repeated, record the first result (invalid or unacceptable), resolve the problem, then record the repeated result(s). Report the final acceptable result only. See Appendix C for examples of QC logs and result logs.

Issuing Test Reports

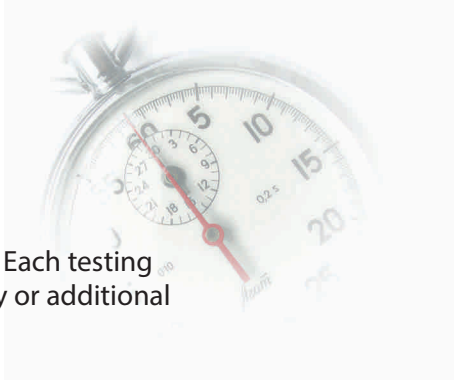
Guidelines for issuing test reports:

- ✓ Patient test reports should be legible, standardized, and reported in a timely manner.
- ✓ Reports from tests conducted on-site should be easily distinguishable from referral laboratory test reports.
- ✓ Patient test reports should only be given to authorized persons.
- ✓ Verbal test reports should be documented and followed by a written test report.

Guidelines for critical values:

Critical values are test results that require immediate treatment or evaluation by the physician. The testing site should establish a system to ensure critical values are addressed by:

- ✓ defining which tests have critical values,
- ✓ ensuring that staff are aware of the critical values and know how to alert the physician in a timely manner, and
- ✓ assuring that staff document when and to whom critical values are reported.



Confirmatory or Supplemental Testing

The manufacturer's instructions should explain when additional testing is required. Each testing site should have written site specific policies and procedures to ensure confirmatory or additional testing is performed or referred, when needed. Instructions should include how to:

- ✓ order additional tests, with examples of completed request forms,
- ✓ contact the referral laboratory, if necessary,
- ✓ collect and label the sample, and
- ✓ transport or ship samples safely: http://www.phmsa.dot.gov/hazmat and http://www.iata.org/publications/dgr/Pages/index.aspx

Sites should maintain records of referred tests that:

- ✓ link the referred sample to the original patient sample,
- ✓ document the referral laboratory, test name and date referred, and
- ✓ document when test results are received and the date of the final test report.

Public Health Reporting

Public health agencies require testing sites to report confirmed positive test results for certain infectious diseases. Testing sites should check with local public health agencies for the most current information on required reporting procedures, since diseases identified for reporting can change over time, and state requirements may vary.

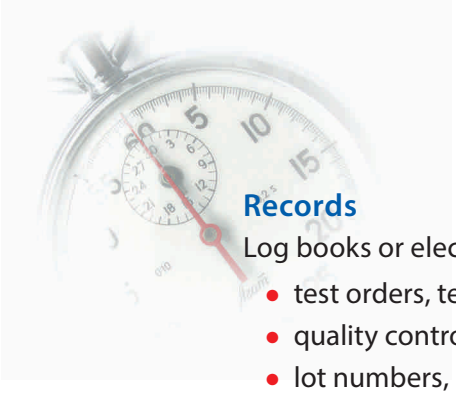
- National Notifiable Diseases Surveillance System: http://wwwn.cdc.gov/nndss/default.aspx
- Public Health Resources: State Health Departments: http://www.cdc.gov/mmwr/international/relres.html

Record Keeping

Document all steps of the testing process to assure quality testing. All equipment logs, maintenance records, QC documents, testing records, and test results should be kept for easy retrieval of information. The person overseeing testing and operations should periodically review records. Good record keeping is necessary to:

- ✓ retrieve and verify information,
- ✓ assess test performance,
- ✓ identify and resolve problems that could affect test results, and
- ✓ maintain patient and personnel information.

Check with your local/state public health department for record keeping requirements.



Records

Log books or electronic files can be used to maintain records. Examples of records include:

- test orders, test results, results from confirmatory or additional testing;
- quality control results;
- lot numbers, dates used and received, and expiration dates of reagents, kits and quality control material;
- daily temperature checks, test system or equipment function checks and maintenance;
- test system failures, troubleshooting, and corrective action taken when problems have been identified;
- test or product recall notices;
- personnel training and competency assessments; and
- results of proficiency testing or other external quality assessment activities.

Proficiency Testing

Although proficiency testing (PT) is not routinely required for waived testing, there are many benefits of participating in a PT program. PT provides:

- a regular, external check on quality of testing,
- motivation to improve performance,
- comparison of performance with that of other participating sites (peers),
- an opportunity to obtain feedback and technical advice from programs that offer PT,
- assistance in evaluating methods and instrumentation,
- assistance with staff education, training and competence monitoring, and
- opportunities for identifying areas needing improvement.

For information on programs that offer PT, refer to:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf

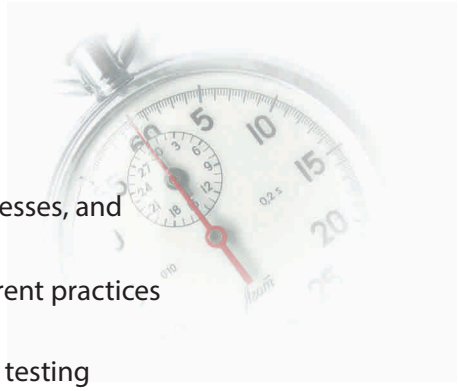
See also CMS brochure 'Proficiency Testing' available online:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/CLIAbrochure8.pdf

Quality Assessment

Assessing testing quality requires planned and systematic monitoring and evaluation of the testing process. Conducting these activities can lead to reduced errors, improved patient outcomes, improved patient and employee safety, and reduced costs. Both internal and/or external mechanisms for quality assessment may be used depending on the needs, resources, and practices of the testing site. Examples are listed below.

Internal assessments are processes for staff performing and overseeing testing to evaluate their current practices, including:

- performing and documenting QC procedures and results,
- reviewing QC records and test results,
- reviewing room and refrigerator temperature log sheets for complete documentation,



- documenting and reviewing problems and establishing a plan to improve processes, and
- documenting and reviewing injury/incident reports.

External assessments are typically performed by an outside party to evaluate current practices and offer opportunities for education. Possible options for external review include:

- undergoing voluntary inspections by peers or consultants who would evaluate testing practices and documentation systems, and offer suggestions for improvement.
- subscribing voluntarily to PT programs. PT programs periodically send challenge samples to test like patient specimens; the program then compares the results with an assigned value, and reports the results back to the participating laboratory or testing site. Many PT programs offer modules for waived tests. Although use of a CLIA-approved PT program is not a CLIA requirement, a list of these can be found at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf
- exchanging samples with other testing sites using the same test method(s) to compare results.

Tips, Reminders, and Resources

Ready?

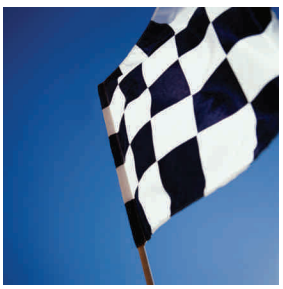
- ☐ Clean work surfaces before and after testing.
- ☐ Perform testing in a well lit area.
- ☐ Check and record temperatures of the testing and reagent storage areas.
- ☐ Check inventory regularly to ensure you will have enough reagents and supplies on hand for testing.
- ☐ Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.
- ☐ Check that all kit reagents came from the same kit lot. Do not mix reagents.
- ☐ Inspect reagents for damage, discoloration, or contamination, and discard if found.
- ☐ Prepare reagents according to manufacturer's instructions.
- ☐ Allow time for refrigerated reagents/samples to come to room temperature prior to testing.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks, as needed, following the manufacturer's instructions.
- ☐ File the old manufacturer's instructions and replace with the new copy if there are changes.
- ☐ Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.
- ☐ Treat and test quality control (QC) samples the same as patient samples.
- ☐ Perform QC as recommended in the manufacturer's instructions.

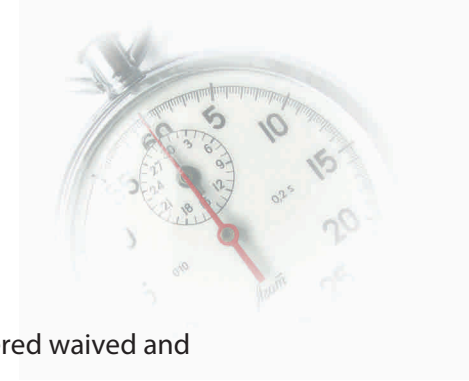
Set?

- ☐ Check patient identification and test orders.
- ☐ Discuss pretest instructions and counseling needs with the patient.
- ☐ Wear appropriate personal protective equipment (PPE) such as gloves.
- ☐ Collect and label a good sample for testing.
- ☐ Clean hands and change gloves between patients.
- ☐ Use the proper biohazard containers to dispose of waste and sharps.

Test!

- ☐ Do not test samples that are improperly collected or handled.
- ☐ Have the manufacturer's instructions or a quick reference guide at the work station.
- ☐ Follow the manufacturer's instructions in the exact order.
- ☐ Follow required timing for testing.
- ☐ Identify and correct problems before reporting test results.
- ☐ Identify and report critical values in a timely manner.
- ☐ Perform or refer confirmatory or additional testing, if needed.
- ☐ Make sure patient reports are legible and reported in a timely manner.
- ☐ Make sure reports are standardized and easily distinguishable from referral laboratory test reports.
- ☐ Report patient test results only to authorized persons.
- ☐ Document verbal reports, followed by a written test report.
- ☐ Report public health diseases.
- ☐ Dispose of biohazardous waste safely.
- ☐ Participate in proficiency testing (PT).
- ☐ Monitor, evaluate, and improve your current practice.



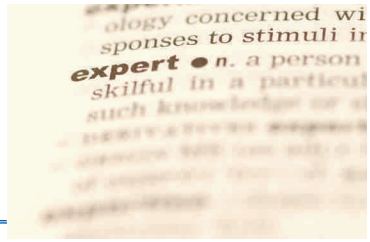


Reminders

- ✓ Have a CLIA Certificate before testing patients.
- ✓ If you have a Certificate of Waiver (CW), use only waived tests or test kits.
- ✓ If a test is modified by the testing laboratory in any way, it is no longer considered waived and cannot be used under a CLIA CW.

Resources

- Appendix F: Terms and Abbreviations
- "Good Laboratory Practices for Waived Testing Sites" Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm
- "READY? SET? TEST!" poster http://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx
- "Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988." http://www.cdc.gov/hiv/pdf/testing_qa_guidlines.pdf
- CLIA: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/
- CLIA CW Application: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
- CLIA – State Agency Contacts: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html
- FDA's CLIA Waived Test List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm
- Health Insurance Portability and Accountability Act (HIPAA): http://www.hhs.gov/ocr/privacy/
- For additional information: http://wwwn.cdc.gov/clia/Resources/WaivedTests/



Safety Links

- The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) Biosafety link: http://www.cdc.gov/biosafety/
- List of OSHA publications and links: http://www.osha.gov/pls/publications/publication.html
- State occupational safety and health programs: http://www.osha.gov/dcsp/osp/index.html

Temperature Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test. This includes instructions for reagents, controls, and patient specimen storage. The manufacturer's instructions will give storage conditions for the product and a temperature range for storing reagents, controls, and patient specimens.

Refrigerators and freezers are important for cooling or freezing the test reagents, controls, and patient samples for preservation. Typically, a refrigerator used to store patient samples is kept between +2 and +8 degrees Celsius. A freezer used for sample storage is often kept between -25 and -15 degrees Celsius. The acceptable temperature range for a freezer or refrigerator is determined by the temperature range indicated for the reagents, controls, and patient specimens that are stored in it.

In order to ensure that a refrigerator or freezer is maintaining the proper temperature, it is important to check and record the temperature daily. This applies whether or not the refrigerator or freezer has a temperature alarm, a chart recorder thermometer, or a digital data logger.

Contents:

There are many ways to log the temperature of a refrigerator or freezer. A blank log is included for your use, along with an example log that demonstrates how to correctly enter site specific information.

1. Example Temperature Log Completed.
2. Blank Temperature Log.
3. Example Temperature Log for Multiple Instruments Completed.
4. Blank Temperature Log for Multiple Instruments.

Instructions for Recording Temperatures:

1. Post a temperature log on the refrigerator and/or freezer door.
2. Read the thermometer(s) in the refrigerator and/or freezer daily.
3. Check for separated columns, gas bubbles, and cracks each time the thermometer is read, as applicable.
4. Record the temperature(s) of the refrigerator and/or freezer.
5. Date and initial/sign the temperature log.
6. If a temperature reading is missed, the blank log entry should remain blank. Do not make up or guess what the temperature was for that reading.
7. Document action when the temperature in the refrigerator and/or freezer falls outside the recommended range for storage.
8. The person who directs or supervises the testing should review and sign when the temperature log is completed for the month.

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 55555

TEMPERATURE LOG

Refrigerator/freezer Location lab refrigerator **Month/Year** June 2015

Acceptable temperature range 4-8°C

Date	Temperature	Checked by:	Date	Temperature	Checked by:
1	4°C	Sara	17	#	#
2	#	#	18	4°C	Sara
3	#	#	19	4°C	Sara
4	4°C	Sara	20	4°C	CO
5	4°C	Sara	21	4°C	Sara
6	8°C	CO	22*	24°C	Sara
7*	15°C	Sara	23	#	#
8	4°C	Sara	24	#	#
9	#	#	25	4°C	Sara
10	#	#	26	4°C	Sara
11	4°C	Sara	27	4°C	CO
12	4°C	Sara	28	4°C	Sara
13	4°C	CO	29	4°C	Sara
14	4°C	Sara	30	#	#
15	4°C	Sara	31	#	#
16	#	#			

** Enter # for weekends and holidays when temperature is not monitored.*

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
* 6/7	Refrigerator door was ajar. Closed door, check in 30 minutes. Temp at 6°C - OK.	Sara
* 6/22	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed by: Janice Smith, office mgr. **Date:** 6/29/2015

Facility:

Location:

TEMPERATURE LOG

Refrigerator/freezer Location_____ **Month/Year** _____

Acceptable temperature range _____

Date	Temperature	Checked by:	Date	Temperature	Checked by:
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

** Enter # for weekends and holidays when temperature is not monitored.*

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed by: _____ **Date:** _____

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 55555

Temperature Log for Multiple Instruments

Month _____ **Year** _____

Temp/ Acceptable Range	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Room temp/ (18 to 30°C)	25	26	24	22	27	#	#	26	22	20	19	29	#	#	22	23	25	26	22	#	#	23	27	28	25	22	#	#	24	22	26
25°C Incubator/ (23 to 27°C)	25	25	25	25	25	#	#	25	26	25	25	25	#	#	25	25	26	25	25	#	#	25	25	24	25	25	#	#	26	25	25
37°C Incubator/ (35 to 39°C)	37	38	37	36	37	#	#	37	38	38	36	37	#	#	38	35	30*	36	35	#	#	36	37	38	35	36	#	#	38	37	37
Refrigerator/ (2 to 8°C)	5	6	4	5	6	#	#	6	5	4	6	5	#	#	6	6	6	5	5	#	#	6	6	5	6	4	#	#	5	5	6
Freezer/ (-25 to -35°C)	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30
Initials	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO

Temperatures should be read first thing in the morning.

Record temperature in degrees Celsius for all equipment requiring temperature monitoring.

Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.

Comments: * Incubator door left open. Closed door and checked temperature prior to using for testing purposes. Temp was 35.

Reviewed by: Joe Smith, MD **Date:** 4/31/2015

Facility:

Location:

Temperature Log for Multiple Instruments

Month _____ **Year** _____

Temp/ Acceptable Range	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Room temp/ (18 to 30°C)																															
25°C Incubator/ (23 to 27°C)																															
37°C Incubator/ (35 to 39°C)																															
Refrigerator/ (2 to 8°C)																															
Freezer/ (-25 to -35°C)																															
Initials																															

Temperatures should be read first thing in the morning.

Record temperature in degrees Celsius for all equipment requiring temperature monitoring.

Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.

Comments: _____

_____

_____

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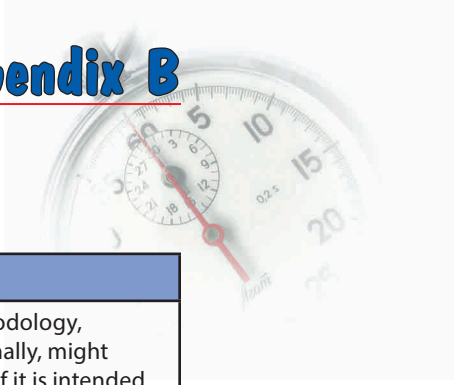
_____

Reviewed by: _____ **Date:** _____



Common Components of a Manufacturer's Instructions

Component	Information Provided
Intended Use	Describes the test purpose, substance detected or measured, test methodology, appropriate specimen type and FDA cleared conditions for use. Additionally, might include if the test is diagnostic or for screening a target population and if it is intended for professional use or self-testing.
Summary	Explains what the test detects; a short history of the methodology, the disease process or health condition detected or monitored; the response to disease, symptoms and severity and disease prevalence and appropriate references.
Test Principle	A description of the test methodology and technical reactions of the test and the interactions with the sample to detect or measure a specific substance.
Precautions	Alerts the user of practices or conditions affecting the test, potential hazards and safety precautions (toxic reagents, handling infectious samples or biohazardous waste). Warnings to not mix components from different lot numbers or use products beyond the expiration date are often included.
Storage and Stability	The recommended conditions for storing reagents or kits; temperature ranges and other physical requirements (humidity, exposure to light) affecting the stability of reagents or test components.
Reagents and Materials Supplied	A list of reagents and materials included in the test kit, the concentration, and major ingredients in reagents.
Materials Required but Not Provided	A description of any additional materials necessary to perform the test that are not provided with the test kit.
Sample Collection and Preparation	A detailed procedure for collecting the appropriate sample including storage and handling instructions. Conditions affecting the acceptability of the sample may be described.
Test Procedure	Step-by-step instructions and information critical to correctly performing the test are provided in this section.
Interpretation of Results	An explanation of how to read or interpret the test results, often includes visual aids. Instructions for dealing with invalid results, precautions against reporting results when supplementary or confirmatory testing is required.
Quality Control	Instructions for performing QC, what aspects of the test are monitored by internal and/or external QC, and when to perform QC testing.
Limitations	Describes the conditions that can affect test results, or circumstances for which the test was not intended, such as: interference from medical conditions, drugs or other substances; limitations for testing with certain samples or populations; more specific testing may be required; warnings that the test does not differentiate between active infection and carrier states, or warnings that test results should be considered with clinical signs, history and other information.
Expected Values	Describes the test results normally expected, how results can vary with disease prevalence or seasonality. Studies leading to the expected results might be included.
Performance Characteristics	Details of the studies done to evaluate the overall performance of the test, including the data for determining accuracy, precision, sensitivity, specificity and reproducibility are present. Additional information from studies of cross-reactivity with interfering substances is included.

Note: Manufacturer's instructions vary in format and some information may be found in different sections than those described here. Testing site directors and testing personnel should read the information provided in the manufacturer's instructions for an understanding of the test and update their procedures, as needed, based on manufacturer's instructions updates.

Appendix C

Quality Control Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test. This includes instructions for quality control (QC).

QC is designed to detect problems that might arise because of reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures provides assurance that the test is performing as expected and alerts the user when problems occur. QC procedures should describe the type of controls to be used, how to perform QC testing, frequency of QC testing, and actions to be taken when QC results are unacceptable.

QC material should be treated the same as patient samples by being tested in the same way that patient samples would be tested. QC is usually performed with:

- each new operator,
- after an instrument is serviced,
- when reagent lots are changed,
- when test kit temperatures exceed the manufacturer's limits,
- after calibration, and
- when patient results seem questionable.

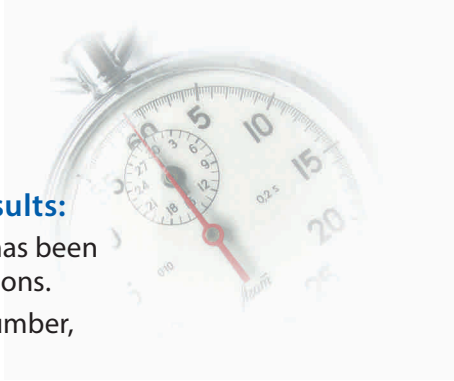
Refer to the manufacturer's instructions for specific QC requirements for each test that your facility performs. Each testing site should determine the appropriate QC frequency for each test system. Keep in mind that the frequency of QC testing cannot be less than what is specified in the manufacturer's instructions.

Contents:

There are many ways to log QC results. A blank QC log is included for your use, along with an example log that demonstrates how to correctly enter site specific information.

1. Example Quality Control-Qualitative Test Log Completed.
2. Blank Quality Control-Qualitative Test Log.
3. Example Quality Control-Quantitative Test Log Completed.
4. Blank Quality Control-Quantitative Test Log.

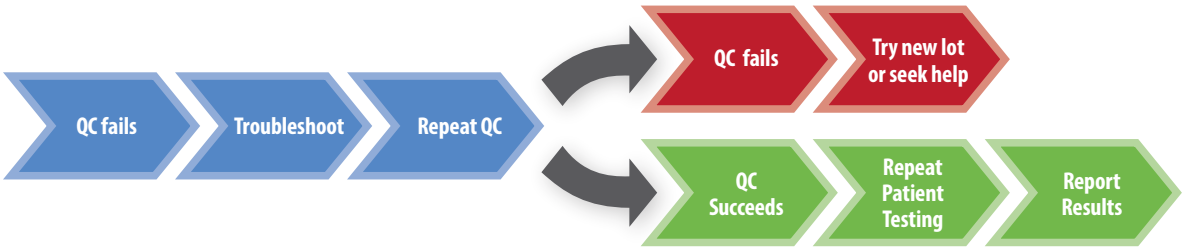
Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.



Instructions for Performing External Control Testing and Recording Results:

1. Obtain the QC material. Check the expiration date and check that the material has been stored and handled according to the manufacturer's requirements and instructions.
2. Record the initials of the person performing the test, test date, test name, lot number, and expiration date of the test on the QC Log.
3. Record the lot number for the QC material on the QC Log.
4. Test the QC material following the manufacturer's instructions and record the results on the QC Log.
5. If the results are acceptable, QC passes, and patient results can be reported.
6. If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the instructions in the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error such as outdated reagents or test devices.
- ✓ Check to see if reagents were stored correctly.
- ✓ Make sure controls or reagents were not cross-contaminated by accidentally switching caps on kit or control vials.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site specific procedure.
- ✓ For additional assistance, contact the manufacturer, technical representative, and/or the person who directs or supervises the testing.
- ✓ Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient samples and report the final acceptable results.



Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Quality Control Log – Qualitative Test

	Tech Initials	Date	Test Name	Test Lot number / Test Exp. Date	Negative Control	Positive Control	Mid- Range Control (if applicable)	Comments	Reviewed by Initials / Date
1	CO	5/5/2008	Occult Blood 1-2-3	Bjz-3 / 8-31-2015	lot #: 108-OCB result: Pos*	lot #: 108-OCB result: Pos	lot #: N/A result:	*possible sample mix-up, retest	Joe Smith 5/5/2015
2	CO	5/5/2008	Occult blood 1-2-3	Bjz-3 / 8-31-2015	lot #: 108-OCB result: Neg	lot #: 108-OCB result: Pos	lot #: N/A result:	QC passed and ready to use	Joe Smith 5/5/2015
3					lot #: result:	lot #: result:	lot #: result:		
4					lot #: result:	lot #: result:	lot #: result:		
5					lot #: result:	lot #: result:	lot #: result:		
6					lot #: result:	lot #: result:	lot #: result:		
7					lot #: result:	lot #: result:	lot #: result:		
8					lot #: result:	lot #: result:	lot #: result:		
9					lot #: result:	lot #: result:	lot #: result:		
10					lot #: result:	lot #: result:	lot #: result:		

Facility:

Location:

Quality Control Log – Qualitative Test

	Tech Initials	Date	Test Name	Test Lot number / Test Exp. Date	Negative Control	Positive Control	Mid- Range Control (if applicable)	Comments	Reviewed by Initials / Date
1					lot #:	lot #:	lot #:		
					result:	result:	result:		
2					lot #:	lot #:	lot #:		
					result:	result:	result:		
3					lot #:	lot #:	lot #:		
					result:	result:	result:		
4					lot #:	lot #:	lot #:		
					result:	result:	result:		
5					lot #:	lot #:	lot #:		
					result:	result:	result:		
6					lot #:	lot #:	lot #:		
					result:	result:	result:		
7					lot #:	lot #:	lot #:		
					result:	result:	result:		
8					lot #:	lot #:	lot #:		
					result:	result:	result:		
9					lot #:	lot #:	lot #:		
					result:	result:	result:		
10					lot #:	lot #:	lot #:		
					result:	result:	result:		

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Quality Control Log – Quantitative Test

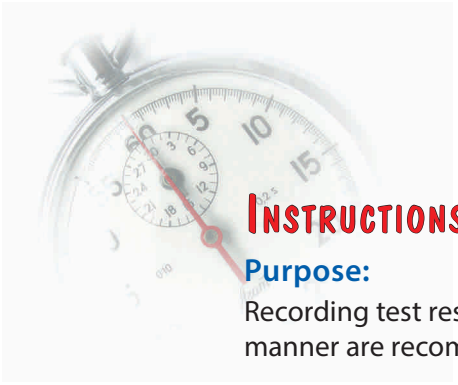
	Tech Initials	Date	Test Name	Test Lot number / Test Exp. Date	Level 1 Control	Level 2 Control	Comments	Reviewed by Initials / Date
1	CO	5/5/2012	XYZ ALT	C843 / 4-31-2015	lot #: 91750566 range: 43-78 U/L result: 31 U/L*	lot #: 91750566 range: 132-242 U/L result: 203 U/L	*Level 1 Control value too low, Kit was expired Discard Kit	Joe Smith 5/5/2015
2	CO	5/5/2012	XYZ ALT	C978 / 8-31-2015	lot #: 91750598 range: 43-78 U/L result: 55 U/L	lot #: 91750598 range: 132-242 U/L result: 221 U/L	New lot. QC passed and Ready to use	Joe Smith 5/5/2015
3					lot #: range: result:	lot #: range: result:		
4					lot #: range: result:	lot #: range: result:		
5					lot #: range: result:	lot #: range: result:		
6					lot #: range: result:	lot #: range: result:		
7					lot #: range: result:	lot #: range: result:		
8					lot #: range: result:	lot #: range: result:		
9					lot #: range: result:	lot #: range: result:		

Facility:

Location:

Quality Control Log – Quantitative Test

	Tech Initials	Date	Test Name	Test Lot number / Test Exp. Date	Level 1 Control	Level 2 Control	Comments	Reviewed by Initials / Date
1					lot #: range: result:	lot #: range: result:		
2					lot #: range: result:	lot #: range: result:		
3					lot #: range: result:	lot #: range: result:		
4					lot #: range: result:	lot #: range: result:		
5					lot #: range: result:	lot #: range: result:		
6					lot #: range: result:	lot #: range: result:		
7					lot #: range: result:	lot #: range: result:		
8					lot #: range: result:	lot #: range: result:		
9					lot #: range: result:	lot #: range: result:		



Instructions for Logging or Recording Results

Purpose:

Recording test results legibly, completely, and filing records in an organized, easy to find manner are recommended practices for all testing.

Contents:

There are many ways to record results. A blank Results log is included for your use, along with an example log that demonstrates how to enter site specific information.

1. Example of Results Log – Qualitative Test Completed.
2. Blank Results Log – Qualitative Test.
3. Example of Results Log – Quantitative Test Completed.
4. Blank Results Log – Quantitative Test.
5. Example of Results Log with QC – Qualitative Test Completed.
6. Blank Results Log with QC – Qualitative Test.
7. Example of Results Log with QC – Quantitative Test Completed.
8. Blank Results Log with QC – Quantitative Test.
9. Example of Results Log for Multiple Tests Completed.
10. Blank Results Log for Multiple Tests.

Instructions for Logging or Recording Results:

Results Log – Qualitative Test

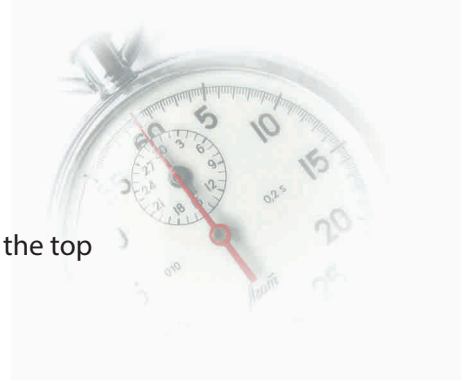
1. Record the facility information and test name on the top of the form.
2. Enter the date of the test, sample number, patient name or identification, test results, lot number and expiration date of test.
3. The person performing the test should initial the results after verifying all of the information has been entered correctly.

Results Log – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Enter the date of the test, sample number, patient name or identification, test results, lot number and expiration date of test.
3. The person performing the test should initial the results after verifying all of the information has been entered correctly.

Results Log with QC – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Record the QC material lot number, expiration date, positive and negative control results.
3. If the results are acceptable, QC passes and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition etc.), re-test the QC and document the corrective action taken.



Results Log with QC – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Record the QC material lot number, reportable range, and result.
3. If the results are acceptable, QC passes and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition etc.), re-test the QC and document the corrective action taken.

Results Log for Multiple Tests

1. Record the facility information on the top of the form.
2. Record the date, sample number, patient identification, test name, reportable range (if applicable), test result, lot number, expiration date, and the initials of the individual performing the test.

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log – Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2015	5/5/2018	Donald Smith	NEG	Bd-0679/ 11-30-2015	CO
2	5/6/2015	5/5/2019	Chris White	POS	Bd-0679/ 11-30-2015	CO
3	5/7/2015	5/6/1930	Sam Jones	NEG	Bd-0679/ 11-30-2015	CO
4						
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14						
15						

Facility:
Location:

Results Log – Qualitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
4						
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6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log – Quantitative Test

Test Name: XYZ Strep antigen

Reportable Range: 5-400 u/L

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2015	5/5/2018	Steve Smith	Male: 30 u/L	Bd-0679/ 11-30-2015	CO
2	5/6/2015	5/5/2019	Chris White	Male: 22 u/L	Bd-0679/ 11-30-2015	CO
3	5/7/2015	5/6/1930	Sam Jones	Female: 14 u/L	Bd-0679/ 11-30-2015	CO
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** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility:

Location:

Results Log – Quantitative Test

Test Name: _____ Reportable Range: _____

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log with QC – Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp Date	Positive Control Results	Negative Control Results
1	5/5/2015	5-05-20 / Tom Jones	NEG	SH	Bd-0679/ 11-30-2015	108-OCB / 9-30-15	POS	NEG
2	5/6/2015	5-05-22 / Mattie Dunn	NEG	CO	Bd-0679/ 11-30-2015	108-OCB / 9-30-15	POS	NEG
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13								
14								
15								

Facility:

Location:

Results Log with QC – Qualitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp Date	Positive Control Results	Negative Control Results
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log with QC – Quantitative Test

Test Name: XYZ Strep antigen

Reportable Range: 5-400 U/L

	Date	Sample ID / Patient ID	Test Results	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1	5/5/2015	5/5/2018 / Steve Smith	Male: 30U/L	CO	C843/06-31-2015	lot #: 91750566 range: 43-78 U/L result: 57 U/L	lot #: 91750566 range: 132-242 U/L result: 203 U/L
2	5/5/2015	5/5/2019 / Chris White	Male: 22U/L	CO	C843/06-31-2015	lot #: 91750566 range: 43-78 U/L result: 58 U/L	lot #: 91750566 range: 132-242 U/L result: 221 U/L
3	5/7/2015	5/5/1930 / Sam Jones	Female: 14U/L	CO	C843/06-31-2015	lot #: 91750566 range: 43-78 U/L result: 57 U/L	lot #: 91750566 range: 132-242 U/L result: 221 U/L
4						lot #: range: result:	lot #: range: result:
5						lot #: range: result:	lot #: range: result:
6						lot #: range: result:	lot #: range: result:
7						lot #: range: result:	lot #: range: result:
8						lot #: range: result:	lot #: range: result:
9						lot #: range: result:	lot #: range: result:

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility:
Location:

Results Log with QC – Quantitative Test

Test Name: _____ Reportable Range: _____

	Date	Sample ID / Patient ID	Test Results	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1						lot #: range: result:	lot #: range: result:
2						lot #: range: result:	lot #: range: result:
3						lot #: range: result:	lot #: range: result:
4						lot #: range: result:	lot #: range: result:
5						lot #: range: result:	lot #: range: result:
6						lot #: range: result:	lot #: range: result:
7						lot #: range: result:	lot #: range: result:
8						lot #: range: result:	lot #: range: result:
9						lot #: range: result:	lot #: range: result:

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility: Dr. Smith's Office

Location: 123 Main Street, Atlanta, GA 55555

Results Log for Multiple Tests

	Date	Sample Number	Patient Name or ID	Test Name	*Reportable Range	Test Result	Test Lot Number / Test Exp. Date	Initials
1	5/5/2015	5/5/2018	Donald Smith	XYZ Strep	NA	NEG	Bd-0679/11-30-2015	CO
2	5/5/2015	5/5/2019	Chris White	XYZ Strep	NA	POS	Bd-0680/11-30-2015	CO
3	5/5/2015	5/5/2020	Tom Jones	Occult blood - 123	NA	NEG	Bjz-3/8-31-2015	SH
4	5/5/2015	5/5/2021	Pam Roberts	Urine HCG-ABC	NA	NEG	Trp-23/11-30-2015	CO
5	5/6/2015	5/5/2022	Mattie Dunn	Occult blood - 123	NA	NEG	Bjz-3/8-31-2015	CO
6	5/6/2015	5/5/2023	Steve Smith	XYZ ALT	5-400 U/L	Male : 33 U/L	C843/6-31-2015	CO
7								
8								
9								
10								
11								
12								
13								
14								
15								

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility:

Location:

Results Log for Multiple Tests

	Date	Sample Number	Patient Name or ID	Test Name	*Reportable Range	Test Result	Test Lot Number / Test Exp. Date	Initials
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Appendix D

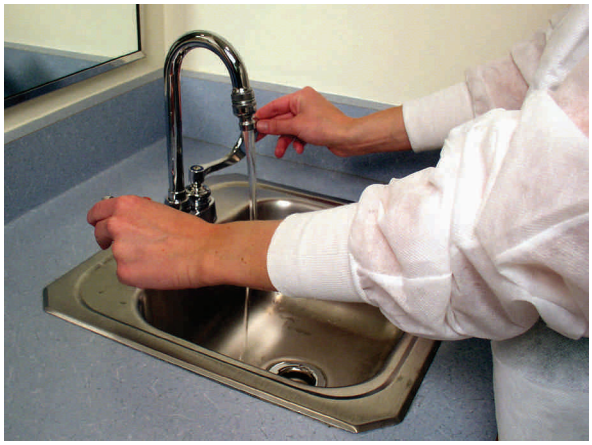
Hand Hygiene Job Aid

The use of disposable gloves does not eliminate the need for cleaning hands. Likewise, handwashing does not eliminate the need for gloves. In order to ensure proper hand hygiene when performing testing, handwashing or alcohol-based gels should be used before and after each patient, just as gloves should be changed between each patient.

Hand Washing Steps

If a hand washing sink is available:

1. Wet hands with warm running water.



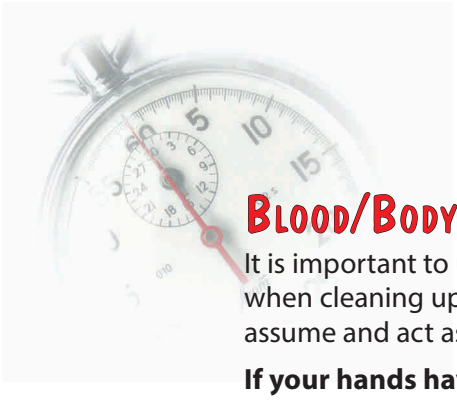
2. Apply soap and rub hands together, covering all surfaces of hands and fingers, for at least 20 seconds.

1. Rinse hands and dry with disposable towel.

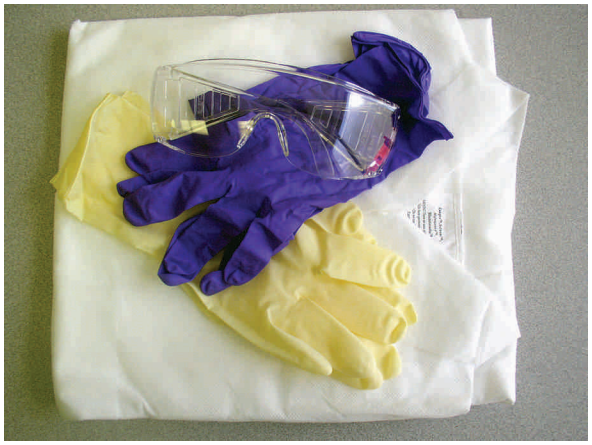
2. Use disposable towel to turn off the faucet and discard in the regular trash.

If a hand washing sink is not available:

1. Use an alcohol-based gel.
2. Follow manufacturer's instructions to determine the amount of alcohol-based gel to use.
3. Apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.
4. Wash hands with soap and water as soon as possible.



Blood/Body Fluid Exposure



It is important to use universal precautions when cleaning up blood or body fluids. Always assume and act as if they are contaminated.

If your hands have been exposed to blood or body fluids:

1. Wet hands with warm running water.
2. Apply soap and vigorously scrub all surfaces of hands and fingers, using large amounts of soap and water.
3. Rinse hands and dry with disposable towel.
4. Use disposable towel to turn off faucet.
5. Before leaving area, decontaminate sink and faucet handles using 10% bleach or Environmental Protection Agency (EPA) registered disinfectant effective against HBV, HIV, and other bloodborne pathogens.

If mucous membranes or eyes have been exposed to blood or body fluids:

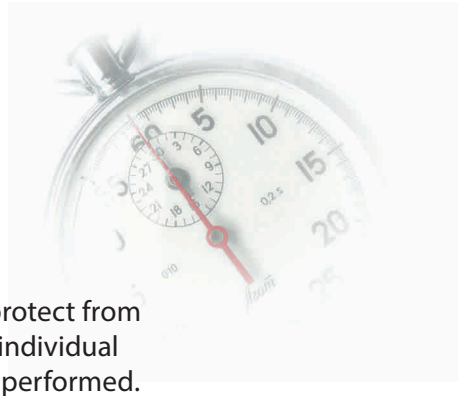
1. Rinse mucous membranes (for example, nose or mouth) or eyes with large amounts of water or saline solution.
2. If running water is not readily available, use another source of water (for example, bottled water) to rinse.

If there is a puncture of skin from a sharp instrument or needle:

1. Wash the puncture with soap and water while encouraging the puncture to bleed (through squeezing if necessary).
2. Bandage the puncture when finished.

Report exposure:

1. Report any exposures to those responsible for managing exposures (for example, occupational health, infection control, management). Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and needs to be started as soon as possible.
2. Discuss the possible risks of acquiring hepatitis B, hepatitis C, and HIV and the need for post-exposure treatment with the provider managing your exposure.



Glove Removal Job Aid

Disposable Gloves (latex, vinyl, nitrile):

Disposable gloves reduce hand contamination, prevent cross-contamination, and protect from infection. Gloves should fit properly, not restrict hand coordination, accommodate individual requirements such as allergy to latex, and meet the requirements of the task being performed. Rings, long fingernails, and fingernail jewelry can make it more difficult to put the gloves on properly and can also cause gloves to tear more easily.

To help prevent allergic reactions to latex gloves:

- Do not use oil-based hand creams or lotions when wearing latex gloves.
- Wash hands with a mild soap and dry thoroughly after removing gloves.
- Do not use powdered latex gloves.

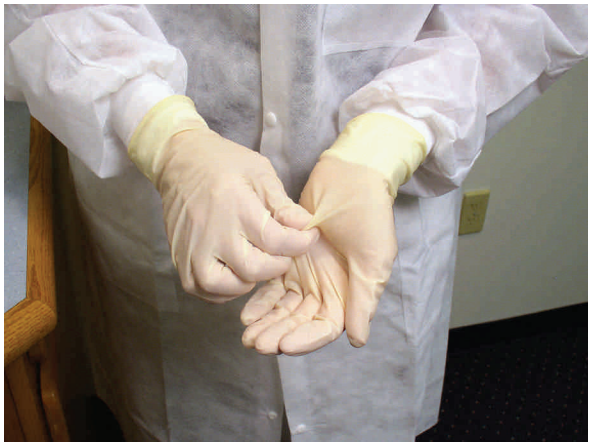
For additional latex allergy information: http://www.cdc.gov/niosh/topics/latex

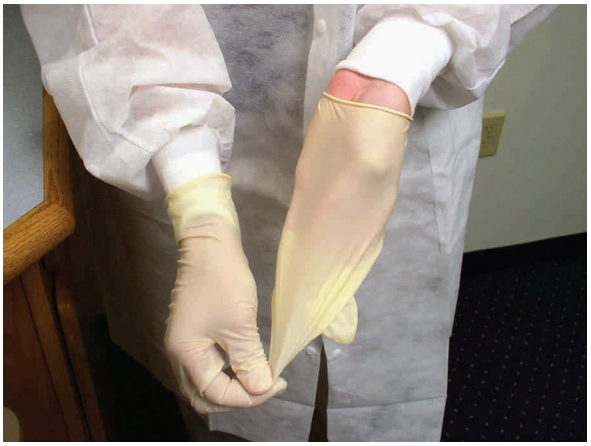
All employees using disposable gloves must observe the following precautions:

- Cover open sores, dermatitis, cuts, etc. with a dressing or bandage.
- Wash hands before putting on gloves.
- Never wash or reuse disposable gloves.
- Remove gloves after they become contaminated as well as before leaving the work area.
- Remove contaminated gloves using a procedure that avoids contact with the outer surface of the glove.
- Dispose of contaminated gloves in infectious waste containers in the work area.
- Wash hands immediately or as soon as possible after removal of gloves.

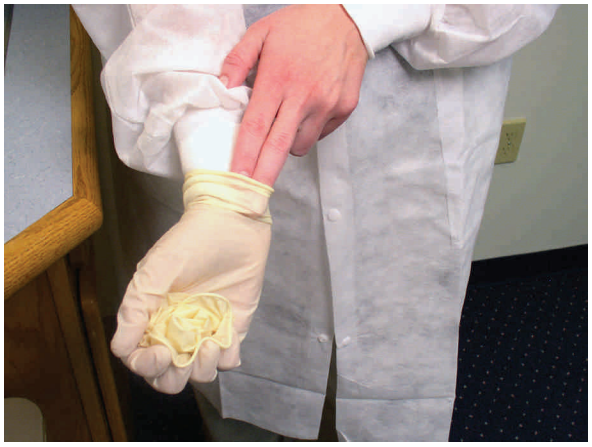
Procedure for Removing Gloves Safely

1. With the right hand, pinch the palm of the left glove and pull left glove down and off your fingers.

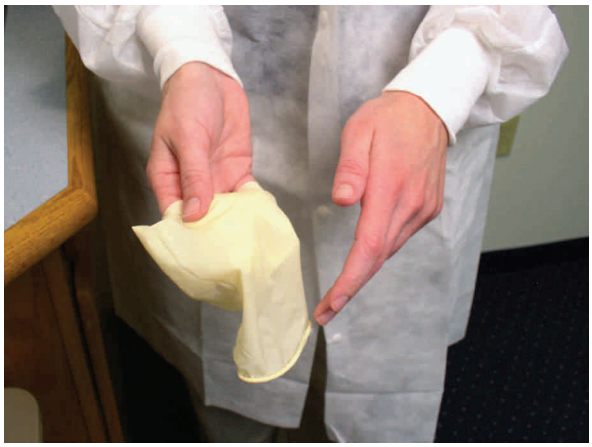


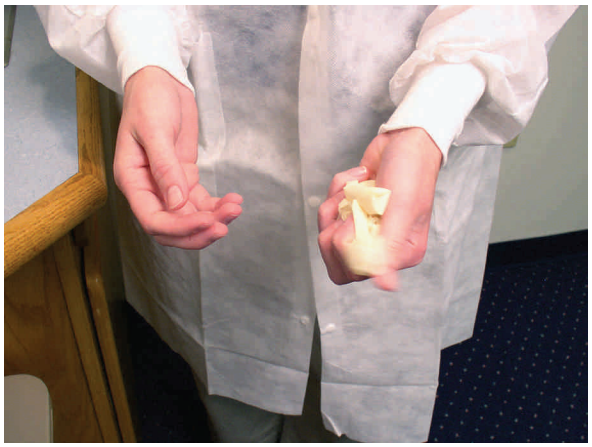


2. Form left glove into a ball and hold it in the fist of your right hand. Insert two fingers of the left hand under the inside rim of your right glove on the palm side.



3. Push glove inside out down onto your fingers and over balled left glove. Grasp gloves, which are inside out and together, with your left hand and remove them from your right hand.





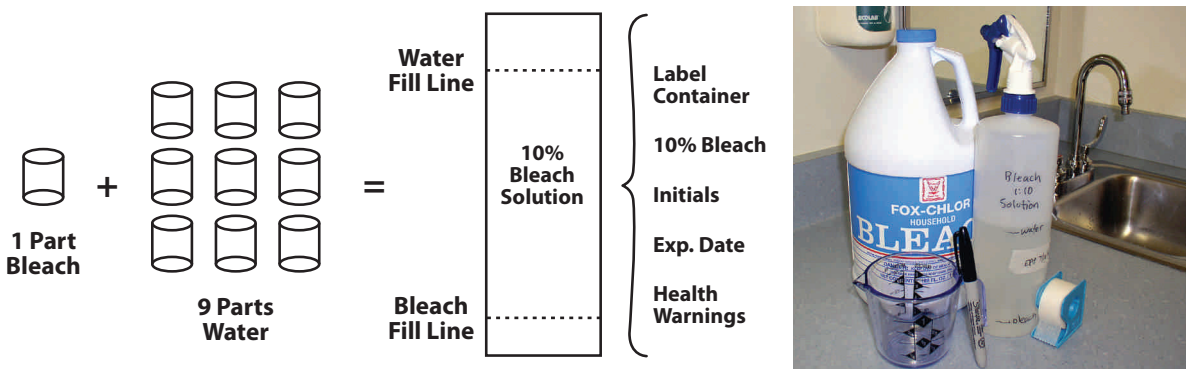
4. Discard gloves into infectious waste container and wash hands.

Common Disinfectants and Antiseptics

Note: Any mention of trade names is for identification purposes only and is not intended as an endorsement. Proprietary disinfectant products should be used in accordance with the manufacturer's instructions for concentration, contact time, or other conditions of use.

Selected EPA-registered disinfectants: A list of EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain bacteria and viruses can be found at: http://www.epa.gov/oppad001/chemregindex.htm

1. **Chlorine compounds** are powerful disinfectants that are inexpensive and easy to obtain. Sodium hypochlorite or household chlorine bleach solutions possess intermediate-level disinfectant properties. For maximum potency, the working solution should be prepared fresh at the time of use or daily as needed, but studies show that weekly preparations work too. A 10% bleach solution is also referred to as 1/10, 1:10 or 5,000 ppm bleach solution.
   The directions for preparation are:



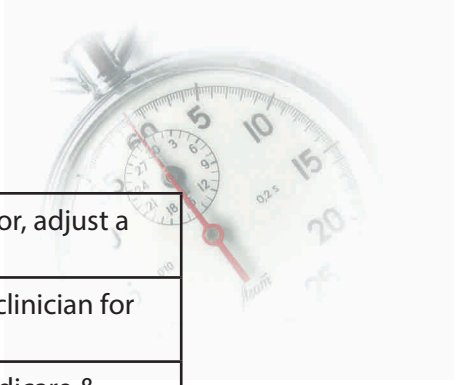
Note: bleach will corrode some equipment. Refer to manufacturer's recommendations for cleaning and disinfecting procedures.

2. **Alcohols** are considered intermediate level disinfectants. Alcohol solutions are often used as a skin antiseptic. Alcohols, such as isopropyl (rubbing) alcohol, are well suited to rapidly kill bacteria on the skin surface in preparation for fingerstick or venipuncture.
3. **Commercial Products.** The EPA provides a list of registered commercial products that are effective against certain bacteria and viruses. Examples are 'Lysol' (cresol and soap solution) and 'Stericol' (xylenol-rich cresylic acid and soap solution)

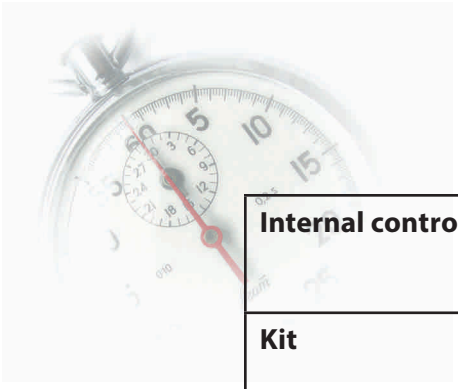
Appendix F

Terms and Abbreviations

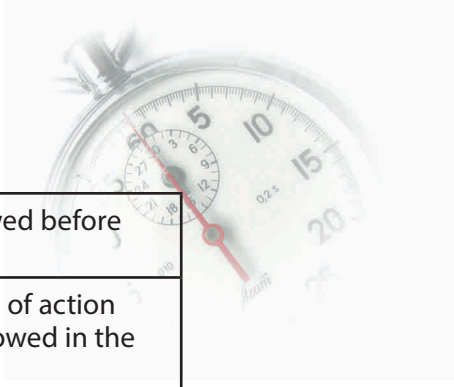
Anticoagulated blood	Blood that has been treated with an anticoagulant. Anticoagulant solutions are used for the preservation of stored whole blood and blood fractions and to keep laboratory blood specimens from clotting.
Biohazard	A biologic substance that can have harmful effects on humans.
Biohazardous waste	Biohazard or sharps waste and waste that is generated or produced as a results of the diagnosis, treatment, or immunization of humans. Environmental laws dictate appropriate, safe disposition of hazardous waste. Refer to applicable federal, state, and local laws.
Biosafety	The application of practices, procedures and safety equipment when working with infectious materials to prevent infection.
Bloodborne pathogens	Microorganisms that, when present in human blood, can cause disease in humans. Examples are hepatitis B and C viruses, and human immunodeficiency virus (HIV).
Calibration check	The process of testing and adjusting an instrument or test system to provide a known relationship between the value of the substance being measured by the test and the test system's measurement response. A calibration check is a mechanism to be sure the test system has remained stable and results remain accurate.
CDC, The Centers for Disease Control and Prevention	A federal agency under the department of Health and Human Services (HHS) that works with partners throughout the nation and world by collaborating to create the expertise, information, and tools that people and communities need to protect their health — through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.
CLIA, The Clinical Laboratory Improvement Amendments of 1988	United States federal regulatory standards that set forth the conditions that all laboratories must meet to be certified to perform testing on human samples.
CMS, The Centers for Medicare and Medicaid	A federal agency under HHS that has the administrative responsibility for the CLIA program.
Collection devices	A container or instrument used for the collection of samples for testing or analysis.
Competency assessment	The evaluation of a person's ability to perform a test and to use a testing device; this includes all aspects of testing, from sample collection to results reporting.
Confirmatory test	An additional more specific test performed to rule out or confirm a preliminary test result to provide a final result.
Control	A device or solution used to monitor a test system to ensure proper test performance and correct results.



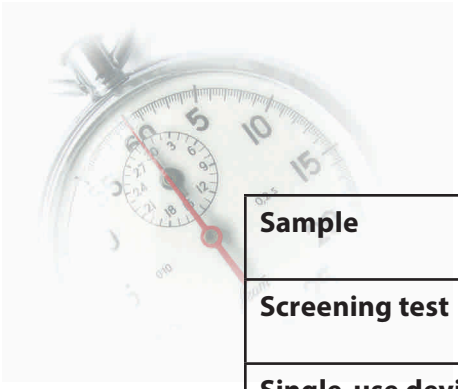
Corrective action	A method used to remedy a situation, remove an error, adjust a condition, or prevent recurrence of a problem.
Critical value	A test result requiring immediate notification to the clinician for patient evaluation or treatment.
CW, Certificate of Waiver	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to a testing site performing only waived tests.
Diagnostic test	Tests likely to provide information which aids in the making of a diagnosis.
Disinfectant	An agent that destroys microorganisms that may cause disease.
EPA, The Environmental Protection Agency	The United States government agency with the mission of protecting human health and the environment.
External control	Control materials that mimic patient samples and monitor the testing process from sample application to result interpretation.
External quality assessment	A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification, whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.
False negative test result	A false negative result is when the test says the patient does not have a disease or condition but they do.
False positive test result	A false positive result is when the test says the patient does have a disease or condition but they do not.
FDA, The Food and Drug Administration	A federal agency under HHS that is responsible for regulating and supervising the safety of biological and medical products and devices as well as categorization of tests under CLIA, including waiver.
Fingerstick	A procedure in which a finger is pricked to obtain a small quantity of capillary blood for testing. Also called a finger prick.
Good laboratory practices	A technique, method, process, activity, incentive or reward that is believed to be more effective at delivering a particular outcome than any other technique, method, or process.
HHS, The Department of Health and Human Services	The United States government's principal agency for protecting the health of all Americans and providing essential human services.
HIPAA, Health Insurance Portability and Accountability Act of 1996	The Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.
Interfering substance	Any substance in a sample, other than the one being measured or detected, whose presence affects the result of the test being performed.



Internal control	Procedural or built-in controls; controls that are built into a testing device and designed to verify that the test system is working as expected.
Kit	A packaged set containing test devices, instructions, reagents and supplies needed to perform a test and generate results.
Log	A record documenting the performance of a machine, the progress of an undertaking, or the results of a task.
Lot	A specific group of articles in a kit. Each article may have a number that can be used as a reference for manufacturing information.
Manufacturer's instructions	Written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test.
Nasopharynx	The area of the upper throat that lies behind the nose.
N, Neg, Negative	A result that indicates the absence of the substance a test is designed to detect.
Negative control	A device or solution used to monitor a test system for proper test performance and correct results. A negative control sample or reagent will produce a negative result on the test system.
NR, Nonreactive	A result that indicates the absence of the substance a test is designed to detect.
Order (test)	A written or verbal request by an authorized individual for a test or procedure to be performed on a patient.
OSHA, The Occupational Safety and Health Administration	The United States government agency with the mission to assure safe and healthful working conditions for all men and women. Workplace standards established and enforced to prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health.
POC, Point of Care	The analysis of clinical specimens as close as possible to the patient.
P, Pos, Positive	A result indicating the presence of a substance a test is designed to detect.
Patient identifiers	The method used to reliably identify the individual as the person for whom the service or treatment is intended, and to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier.
Positive control	A device or solution used to monitor a test system for proper test performance and correct results. A positive control sample or reagent will produce a positive result on the test system.
PPE, Personal protective equipment	Specialized clothing or equipment worn by an employee for protection against a hazard. Examples of PPE are gloves, respirators, lab coats, and safety glasses.



Pretest instructions	Information provided that should be read and followed before testing begins.
Procedure	A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.
Processing (sample)	Any type of treatment a sample undergoes before testing such as spinning of whole blood.
PT, Proficiency testing	An external quality assessment program in which samples are periodically sent to testing sites for analysis.
Public health reporting	A system to notify public health agencies and to monitor the incidence and distribution of communicable, environmental, occupational and other dangerous disease occurrences in populations, as well as factors determining that distribution.
QA, Quality assessment	A group of activities to monitor and evaluate the CW site's entire testing process to help ensure that test results are reliable, improve the testing process, and promote good quality testing practices.
QC, Quality control	The procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.
Qualitative test	A test that detects the presence or absence of a substance or condition in a sample.
Quantitative test	A test that measures the concentration or amount of a substance present in a sample. Results are numerical.
Quick reference instructions	Cards or small signs containing diagrams or flow charts with essential steps for conducting a test that are often included with waived test systems.
R, Reactive	A result indicating the presence of a substance detected by a test.
Reagent	A substance that produces a chemical or biological reaction with the patient sample to detect or measure the substance or condition determined by the laboratory test.
Record	Anything (such as a document, form, log book) providing permanent evidence of or information about past events.
Referral laboratory	A laboratory that receives samples from CW sites (and other laboratories) to perform additional testing, often for follow-up confirmatory testing. The majority of referral laboratories perform nonwaived testing.
Report (test)	A document describing the result or findings of a test.
Reportable range	The span of test result values for which the instrument or test device can accurately measure.
Request (test)	A written or verbal order by an authorized individual for a test or procedure to be performed on a patient.



Sample	A specimen of fluid, blood or tissue collected for analysis on the assumption that it represents the composition of the whole.
Screening test	Tests used to detect a disease in individuals without signs or symptoms of that disease.
Single-use device	A device intended by the manufacturer to be used on one patient during one procedure.
Supplemental testing	A test performed that increases the reliability of reported test results or provides additional information about the sample.
Temperature range	The numerical difference between the minimum and maximum values of temperature observed in a system.
Test system	The instructions and all the instrumentation, reagents and supplies needed to perform a test and generate results.
Testing site	The location where testing is actually conducted. In some instances, laboratories do not stay at a fixed location (e.g., mobile units providing laboratory testing, health screening fairs, or other temporary testing locations). In these cases, the testing site for the laboratory is where the test is performed.
Universal Precautions	An approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bacteria and viruses.
Unprocessed samples	Samples that are not subjected to any type of treatment prior to testing such as centrifugation of whole blood.
Venipuncture	The puncture of a vein through the skin in order to withdraw blood for analysis.
Verbal report	An oral documentation describing the findings of a test or assay.
WT, Waived testing	Test systems, assays or examinations that have been cleared by the FDA for home use, or have been determined to meet the CLIA criteria of being a simple test with an insignificant risk for an erroneous result.
Whole blood	Blood containing all its cellular components that has not undergone centrifugation or had the plasma removed.

For additional information go to: http://wwwn.cdc.gov/clia/Resources/WaivedTests/
Contact the Division of Laboratory Science and Standards at WaivedTesting@cdc.gov
or by calling 404-498-2290.

June 2015

EXHIBIT J

Tackling Reagent Lot-to-Lot Verification in the Clinical Laboratory

Author: Alicia Algeciras-Schimnich, PhD, DABCC // **Date:** JUL.1.2014 // **Source:** Clinical Laboratory News

Topics: Lab Management, Immunochemical

Verifying new reagent lot performance is a common task in the clinical laboratory. It is not only considered good laboratory practice, but also laboratory regulations and accreditation standards require the evaluation of each new reagent lot prior to use. Each new reagent lot has the potential to affect quality control (QC) material and/or patient sample performance. In the clinical laboratory, immunoassays have been reported to be more prone to lot-to-lot variability than general chemistry tests. Multiple factors can affect performance of a new reagent lot, including changes in a critical reagent material or in stability of the reagents, reagent damage during transportation or storage, or incorrect calibration.

Assuring lot-to-lot consistency is particularly critical when an analyte is used for long-term follow-up of patients, as in the case with tumor markers, when small changes in concentration might trigger further laboratory testing, imaging, or other clinical interventions. Reagent manufacturers have procedures in place to qualify the release of new reagent lots. The goal of the manufacturer should be to achieve correct recovery of the analyte, meaning that the assay is able to measure the analyte correctly based on a known expected concentration.

Manufacturers also seek to minimize lot-to-lot variation when recovering patient samples. Unfortunately, manufacturers' processes to ensure lot-to-lot consistency vary greatly and their accessibility to patient samples sometimes is limited. Consequently, they might miss changes that appear once a laboratory tests enough patient samples.

Clinical laboratory practices for lot-to-lot evaluation also vary widely, ranging from testing as few as three-to-four samples to as many as 20to 40 samples with each new reagent lot. Regarding the choice of samples that are tested, current approaches include the use of QC material supplied by the reagent vendors, third party QC material, in-house QC material, and patient samples. Caution should be taken if only QC material is used for lot verification. Matrix-related differences between patient samples and QC material could affect how well QC results reflect new reagent lot performance in actual patient samples.

When patient sample comparisons are used, the type of samples tested again varies significantly between laboratories. Some labs might test samples with low, mid and high analyte concentrations; others might test randomly selected samples, while still others might test samples with values that span the analytical measurement range. There are no universally agreed upon acceptance or rejection criteria for new reagent lots. It is up to the laboratory management team to determine what is acceptable. The decision should be based on the historical performance of the assay, the assay impression, and the estimated allowable overall bias for the respective analyte, given its biological variability and clinical use.

To date, there has not been a standardized protocol or guideline to help laboratories deal with lot-to-lot verification. Recognizing the need for one, the Clinical and Laboratory Standards Institute (CLSI) recently published the document EP26-A—*User Evaluation of Between-Reagent Lot Variation.* This guideline offers a practical protocol that takes into consideration the resource constraints of the clinical laboratory and uses as few patient samples as possible. In practice, the protocol is broken down into two phases.

The first phase –which could be time consuming, but once established, does not need to be repeated– involves gathering data to establish a number of parameters. These include: the maximum difference between the two reagents lots that would be acceptable without having an adverse clinical impact (critical difference); the laboratory-observed method imprecision; and the desired statistical power for detecting significant lot-to-lot changes. This information is then used to determine the number of samples to be tested and the rejection limit necessary to assure the critical difference is detected.

The second phase involves verification of the new reagent lot by testing the determined number of patient samples with both lots of reagents, calculating the average concentration differences between the two lots, and analyzing acceptability of the new lot based on the rejection limit established during the first phase.

Lot-to-lot verification is, without a doubt, necessary to prevent use of suboptimal reagent lots, but it can be an additional burden to the laboratory, especially when it takes multiple attempts to obtain an acceptable reagent lot. Laboratories need to plan ahead and allow time for performing repeat new reagent lot evaluations if acceptability limits are not initially met. Accessibility to the necessary number of patient samples, availability of resources such as instrument time, remaining inventory of the current reagent lot, and technologist time also need to be taken into consideration. With EP26-A, laboratories will be able to adapt a standardized and practical process for lot-to-lot verification, in keeping with resource constraint limits of the current healthcare environment.

Alicia Algeciras-Schimnich, PhD, is an associate professor of Laboratory Medicine and Pathology at the Mayo Clinic in Rochester, Minnesota. She serves as director of Mayo's Clinical Immunoassay Laboratory and associate medical director of operations for Mayo Medical Laboratories.

EXHIBIT K

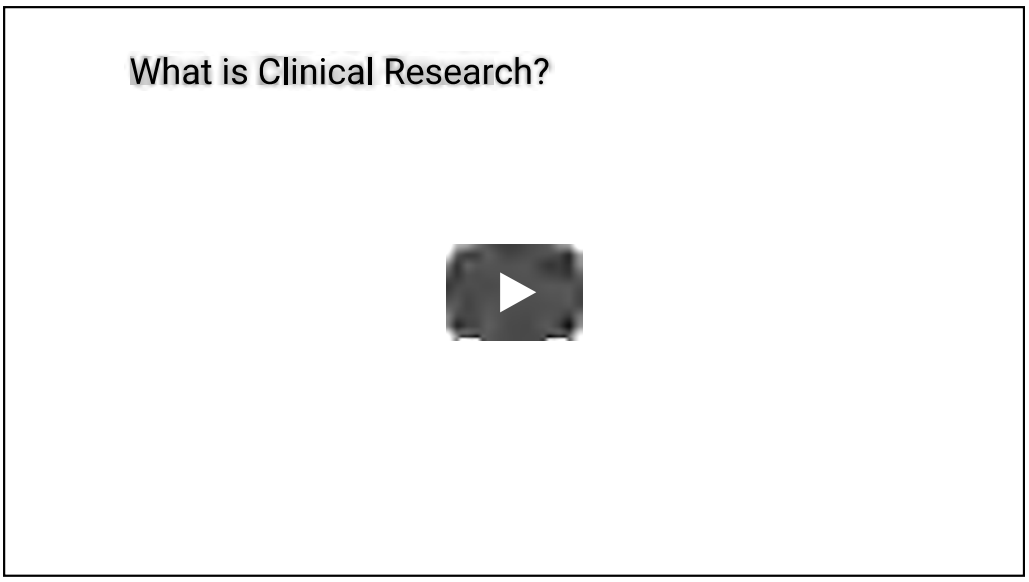
Clinical Research Versus Medical Treatment

en español (/patients/clinical-research-versus-medical-treatment/la-investigacion-clinica-versus-el-tratamiento-medico)

What is clinical research?

Clinical research refers to studies in which people participate as patients or healthy volunteers. Different terms are used to describe clinical research, including:

What is Clinical Research



Read the What is Clinical Research? text alternative (https://www.nichd.nih.gov/health/clinicalresearch/Pages/clinical_research_VTA.aspx)

- clinical studies
- clinical trials
- studies
- research
- trials
- protocols.

Clinical research may have a number of goals, such as:

- developing new treatments or medications

- identifying causes of illness
- studying trends
- evaluating ways in which genetics may be related to an illness.

The idea for a clinical research study—also known as a clinical trial—often starts in the laboratory. After researchers test new therapies or procedures in the laboratory and in animal studies, the most promising experimental treatments are moved into clinical trials, which are conducted in phases. During a trial, more information is gained about an experimental treatment, its risks, and its effectiveness.

Strict rules for clinical studies have been put in place by National Institutes of Health (http://patientnetwork.fda.gov/) and the FDA. Some studies involve promising new treatments that may directly benefit participants. Others do not directly benefit participants, but may help scientists learn better ways to help people.

Confidentiality is an important part of clinical research and ensures that personal information is seen only by those authorized to have access. It also means that the personal identity and all medical information of clinical trial participants is known only to the individual patient and researchers. Results from a study will usually be presented only in terms of trends or overall findings and will not mention specific participants.

Clinical research is much different from the medical treatment you receive in a Healthcare Provider's office.

Clinical Research Versus Medical Treatment

	Clinical Research	**Medical Treatment**
Intent	Answers specific questions through research involving numerous research volunteers.	Address the needs of individual patients.
Intended Benefit	Generally designed and intended to benefit future patients.	Intended to benefit the individual patient.
Funding	Paid for by drug developers and government agencies.	Funded by individual patients and their health plans.
Timeframe	Depends on the research protocol.	Requires real-time decisions.
Consent	Requires written informed consent.	May or may not require informed consent.
Assessment	Involves periodic and systematic assessment of patient data.	Based on as-needed patient assessment.

Protections	Protected by government agencies, institutional review boards, professional standards, informed consent, and legal standards.	Guided by state boards of medical practice, professional standards, peer review, informed consent, and legal standards.
Certainty	Tests products and procedures of unproven benefit to the patient.	Uses products and procedures accepted by the medical community as safe and effective.
Access to Information	Considered confidential intellectual property.	Available to the general public through product labeling.
Release of Findings	Published in medical journals, after clinical research ends.	Individual medical records are not released to the general public.

Who should consider clinical trials and why?

Some people participate in clinical trials because none of the standard (approved) treatment options have worked, or they are unable to tolerate certain side effects. Clinical trials provide another option when standard therapy has failed. Others participate in trials because they want to contribute to the advancement of medical knowledge.

All clinical trials have guidelines, called eligibility criteria, about who can participate. The criteria are based on such factors as age, sex, type and stage of disease, previous treatment history, and other medical conditions. This helps to reduce the variation within the study and to ensure that the researchers will be able to answer the questions they plan to study. Therefore, not everyone who applies for a clinical trial will be accepted.

It is important to test drugs and medical products in the people they are meant to help. It is also important to conduct research in a variety of people, because different people may respond differently to treatments. FDA seeks to ensure that people of different ages, races, ethnic groups, and genders are included in clinical trials. Learn more about FDA's efforts to increase diversity in clinical trials (/patients/clinical-trials-what-patients-need-know/diversity-clinical-trial-participation).

Where are clinical trials conducted?

Clinical trials can be sponsored by organizations (such as a pharmaceutical company), Federal offices and agencies (such as the National Institutes of Health or the U.S. Department of Veterans Affairs), or individuals (such as doctors or health care providers). The sponsor determines the location(s) of the trials, which are usually conducted at universities, medical centers, clinics, hospitals, and other Federally or industry-funded research sites.

Are clinical trials safe?

FDA works to protect participants in clinical trials and to ensure that people have reliable information before deciding whether to join a clinical trial. The Federal government has regulations and guidelines for clinical research (/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection) to protect participants from unreasonable risks. Although efforts are made to control the risks to participants, some may be unavoidable because we are still learning more about the medical treatments in the study.

The government requires researchers to give prospective participants complete and accurate information about what will happen during the trial. Before joining a particular study, you will be given an informed consent document that describes your rights as a participant, as well as details about the study, including potential risks. Signing it indicates that you understand that the trial is research and that you may leave at any time. The informed consent is part of the process that makes sure you understand the known risks associated with the study.

What should I think about before joining a clinical trial?

Before joining a clinical trial, it is important to learn as much as possible. Discuss your questions and concerns with members of the health care team conducting the trial. Also, discuss the trial with your health care provider to determine whether or not the trial is a good option based on your current treatment. Be sure you understand:

- what happens during the trial
- the type of health care you will receive
- any related costs once you are enrolled in the trial
- the benefits and risks associated with participating.

What is FDA's role in approving new drugs and medical treatments?

FDA makes sure medical treatments are safe and effective for people to use. We do not develop new therapies or conduct clinical trials. Rather, we oversee the people who do. FDA staff meet with researchers and perform inspections of clinical trial study sites to protect the rights of patients and to verify the quality and integrity of the data.

Learn more about the Drug Development Process (http://wcms.fda.gov/FDAgov/ForPatients/Approvals/Drugs/default.htm).

Where can I find clinical trials?

One good way to find out if there are any clinical trials that might help you is to ask your doctor. Other sources of information include:

- FDA Clinical Trials Search (/clinical-trials-what-patients-need-know). Search a database of Federally and privately supported studies available through clinicaltrials.gov. Learn about each trial's purpose, who can participate, locations, and who to contact for more information.
- Clinicaltrials.gov. (http://www.clinicaltrials.gov/) Conduct more advanced searches
- National Cancer Institute (http://www.cancer.gov/clinicaltrials/search) or call 1–800–4–CANCER (1–800–422–6237). Learn about clinical trials for people with cancer.

What is a placebo and how is it related to clinical trials?

A placebo is a pill, liquid, or powder that has no treatment value. It is often called a sugar pill. In clinical trials, experimental drugs are often compared with placebos to evaluate the treatment's effectiveness.

Is there a chance I might get a placebo?

In clinical trials that include placebos, quite often neither patients nor their doctors know who is receiving the placebo and how is being treated with the experimental drug. Many cancer clinical trials, as well as trials for other serious and life-threatening conditions, do not include placebo control groups. In these cases, all participants receive the experimental drug. Ask the trial coordinator whether there is a chance you may get a placebo rather than the experimental drug. Then, talk with your doctor about what is best for you.

How do I find out what Phase a drug is in as part of the clinical trial?

Talk to the clinical trial coordinator to find out which phase the clinical trial is in. Learn more about the different clinical trial phases (/patients/drug-development-process/step-3-clinical-research#phases) and whether they are right for you.

What happens to drugs that don't make it out of clinical trials?

Most drugs that undergo preclinical (animal) research never even make it to human testing and review by the FDA. The drug developers go back to begin the development process using what they learned during with their preclinical research. Learn more about drug development (/patients/drug-development-process/step-3-clinical-research).

Learn more about the basics of clinical trial participation, read first hand experiences from actual clinical trial volunteers, and see explanations from researchers at the NIH Clinical Research Trials and You (http://www.nih.gov/health/clinicaltrials/) Web site.

- developing new treatments or medications

- identifying causes of illness
- studying trends
- evaluating ways in which genetics may be related to an illness.