

AREA A
2012 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NCSLPH CLIA Contract Program, in conjunction with manufacturers' instructions.

MODERATE COMPLEXITY PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Glucose	2 levels	Each day of testing
Urine Microscopy	Abnormal	Each week of testing
GC-Lect Media	Observe condition Check sterility	Each plate <i>at time of use</i> Each lot & shipment
GC Testing: a. Oxidase Test b. Gram Stain	a. Positive & negative b. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed; more frequently if required by manufacturer
Wet Mount	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
Urine Colony Count Media	Observe condition Check sterility	Each day of use Each lot & shipment
Syphilis Serology*	a. Reactive, WR, and NR b. Needle c. Rotator count d. Room temperature e. Timer	a. Each day of testing b. Once per vial of antigen, each new needle c. Each day of testing d. Each day of testing e. Once per month with patient testing
WAIVED PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Glucose	2 levels	Each day of testing
Hemoglobin	2 levels	Each day of testing
Hemoglobin A_{1c} a. DCA 2000 b. Bayer A1c Now+ c. Afinion AS100	a. 2 levels 1 level (alternating) b. 2 levels c. 2 levels	a. Each new lot #; New kit; same lot # b. Each new monitor c. <i>Each new lot, new shipment, new employee, and at least every 30 days</i>
Urine Dipstick: a. Visual/Manual Method b. Automated c. Automated (Clinitek Status only)	a. Abnormal only b. Normal & abnormal c. Normal & abnormal	a. Each <u>week</u> of testing, and with each new can of strips b. Each <u>day</u> of testing, and with each new can of strips c. Each <u>week</u> of testing, and with each new can of strips
Urine Pregnancy/hCG**	Positive & negative	Each week of testing and each new kit/container
Rapid Test, Group A Strep**	Positive & negative	Each new kit and at least monthly with patient testing.
Fecal Occult Blood**	Written procedure Proper training	
Amine	Written procedure Proper training	

*Quantitative results require a reactive control of graded or titered reactivity.

**Internal performance monitor result must be recorded for each patient.

AREA B
2012 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NCSLPH CLIA Contract Program, in conjunction with manufacturers' instructions.

MODERATE COMPLEXITY PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Urine Microscopy	Abnormal	Each week of testing
GC-Lect Media	Observe condition Check sterility	Each plate <i>at time of use</i> Each lot & shipment
GC Testing: a. Oxidase Test b. Gram Stain	a. Positive & negative b. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed; more frequently if required by manufacturer
Wet Mount	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
Urine Colony Count Media	Observe condition Check sterility	Each day of use Each lot & shipment
WAIVED PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Cholesterol, Total	2 levels	Each day of testing
Glucose	2 levels	Each day of testing
Hemoglobin	2 levels	Each day of testing
Hemoglobin A_{1c} a. DCA 2000 b. Bayer A1c Now+ c. Afinion AS100	a. 2 levels 1 level (alternating) b. 2 levels c. 2 levels	a. Each new lot #; New kit; same lot # b. Each new monitor c. <i>Each new lot, shipment, new employee, and at least every 30 days</i>
Urine Dipstick: a. Visual/Manual Method b. Automated c. Automated (Clinitek Status only)	a. Abnormal only b. Normal & abnormal c. Normal & abnormal	a. Each <u>week</u> of testing, and with each new can of strips b. Each <u>day</u> of testing, and with each new can of strips c. Each <u>week</u> of testing, and with each new can of strips
Urine Pregnancy/hCG*	Positive & negative	Each week of testing and each new kit/container
Rapid Test, Group A Strep*	Positive & negative	Each new kit and at least monthly with patient testing
Fecal Occult Blood*	Written procedure Proper training	
Amine	Written procedure Proper training	

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AREA C
2012 Quality Control Requirements

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MODERATE COMPLEXITY PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Urine Microscopy	Abnormal	Each week of testing
GC-Lect Media	Observe condition Check sterility	Each plate <i>at time of use</i> Each lot & shipment
GC Testing: a. Oxidase Test b. Gram Stain	a. Positive & negative b. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed; more frequently if required by manufacturer
Wet Mount	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
Urine Colony Count Media	Observe condition Check sterility	Each day of use Each lot & shipment
Syphilis Serology*	a. Reactive, WR and NR b. Needle c. Rotator count d. Room temperature e. Timer	a. Each day of testing b. Once per vial of antigen, each new needle c. Each day of testing d. Each day of testing e. Once per month with patient testing
WAIVED PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Glucose	2 levels	Each day of testing
Hemoglobin	2 levels	Each day of testing
Hemoglobin A_{1c} a. DCA 2000 b. Bayer A1c Now+ c. Afinion AS100	a. 2 levels 1 level (alternate) b. 2 levels c. 2 levels	a. Each new lot # New kit; same lot b. Each new monitor c. <i>Each new lot, shipment, new employee and at least every 30 days</i>
Urine Dipstick: a. Visual/Manual Method b. Automated c. Automated (Clinitek Status only)	a. Abnormal only b. Normal & abnormal c. Normal & abnormal	a. Each <u>week</u> of testing, and with each new can of strips b. Each <u>day</u> of testing, and with each new can of strips c. Each <u>week</u> of testing, and with each new can of strips
Urine Pregnancy/hCG**	Positive & negative	Each week of testing and each new kit/container
Rapid Test, Group A Strep**	Positive & negative	Each new kit and at least monthly with patient testing.
Fecal Occult Blood**	Written procedure Proper training	
Amine	Written procedure Proper training	

*Quantitative results require a reactive control of graded or titered reactivity.

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AREA D
2012 Quality Control Requirements

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GC-Lect Media	Observe condition Check sterility	Each plate <i>at time of use</i> Each lot & shipment
GC Testing: a. Oxidase Test b. Gram Stain	a. Positive & negative b. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed; more frequently if required by manufacturer
Wet Mount	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
Syphilis Serology*	a. Reactive, WR, and NR b. Needle c. Rotator count d. Room temperature e. Timer	a. Each day of testing b. Once per vial of antigen, each new needle c. Each day of testing d. Each day of testing e. Once per month with patient testing
WAIVED PROCEDURES		
TEST	REQUIREMENTS	FREQUENCY
Cholesterol	2 levels	Each day of testing
Glucose	2 levels	Each day of testing
Hemoglobin	2 levels	Each day of testing
Hemoglobin A_{1c} a. DCA 2000 b. Bayer A1c Now+ c. Afinion AS100	a. 2 levels 1 level (alternate) b. 2 levels c. 2 levels	a. Each new lot # New kit; same lot b. Each new monitor c. <i>Each new lot, shipment, new employee and at least every 30 days</i>
Urine Dipstick: a. Visual/Manual Method b. Automated c. Automated (Clinitek Status only)	a. Abnormal only b. Normal & abnormal c. Normal & abnormal	a. Each <u>week</u> of testing, and with each new can of strips b. Each <u>day</u> of testing, and with each new can of strips c. Each <u>week</u> of testing, and with each new can of strips
Urine Pregnancy/hCG**	Positive & negative	Each week of testing and each new kit/container
Rapid Test, Group A Strep**	Positive & negative	Each new kit and at least monthly with patient testing.
Fecal Occult Blood**	Written procedure Proper training	
Amine	Written procedure Proper training	

*Quantitative results require a reactive control of graded or titered reactivity.

**Internal performance monitor result must be recorded for each patient.