

AREA A

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	QC REQUIREMENTS	QC FREQUENCY
URINE MICROSCOPY	Abnormal	Each week of testing; more frequently if required by manufacturer
MTM MEDIA	1. Check sterility 2. Observe condition	1. Each lot and shipment 2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	1. Positive and Negative 2. Positive and Negative	1. Each day of use 2. Each week of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS SEROLOGY	1. Reactive, WR, and NR 2. Needle 3. Rotator speed 4. Room temperature 5. Timer	1. Each day of testing 2. Once per vial of antigen, each new needle 3. Each day of testing 4. Each day of testing (and each batch) 5. Once per month with patient testing
WAIVED PROCEDURES		
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A _{1c}	2 Levels	Each new lot, new shipment, new employee, at least monthly with patient testing
URINE DIPSTICK 1. Visual/Manual Method 2. Automated	1. Normal and Abnormal 2. Normal and Abnormal	1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing
URINE PREGNANCY/hCG*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID INFLUENZA A/B*	Positive and Negative	According to manufacturer's instructions
RAPID SYPHILIS*	<i>Positive and Negative</i>	<i>Each day of testing</i>
FECAL OCCULT BLOOD*	Written procedure and proper training	According to manufacturer's instructions
AMINE	Written procedure and proper training	
URINE DRUG SCREEN	Positive and Negative	According to manufacturer's instructions

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

AREA B

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	QC REQUIREMENTS	QC FREQUENCY
URINE MICROSCOPY	Abnormal	Each week of testing; more frequently if required by manufacturer
MTM MEDIA	1. Check sterility 2. Observe condition	1. Each lot and shipment 2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	1. Positive and Negative 2. Positive and Negative	1. Each day of use 2. Each week of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
WAIVED PROCEDURES		
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A_{1c}	2 Levels	Each new lot, new shipment, new employee, at least monthly with patient testing
URINE DIPSTICK 1. Visual/Manual Method 2. Automated	1. Normal and Abnormal 2. Normal and Abnormal	1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing
URINE PREGNANCY/hCG*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID INFLUENZA A/B*	Positive and Negative	According to manufacturer's instructions
RAPID COVID-19*	Positive and Negative	Each new lot, new shipment, and new employee.
FECAL OCCULT BLOOD*	Written procedure and proper training	According to manufacturer's instructions
AMINE	Written procedure and proper training	

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

AREA C

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	QC REQUIREMENTS	QC FREQUENCY
URINE MICROSCOPY	Abnormal	Each week of testing; more frequently if required by manufacturer
MTM MEDIA	1. Check sterility 2. Observe condition	1. Each lot and shipment 2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	1. Positive and Negative 2. Positive and Negative	1. Each day of use 2. Each week of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS CARD TEST	1. Reactive, WR, and NR 2. Needle 3. Rotator speed 4. Room temperature 5. Timer	1. Each day of testing 2. Once per vial of antigen, each new needle 3. Each day of testing 4. Each day of testing (and each batch) 5. Once per month with patient testing
WAIVED PROCEDURES		
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A _{1c}	2 Levels	Each new lot, new shipment, new employee, at least monthly with patient testing
URINE DIPSTICK 1. Visual/Manual Method 2. Automated	1. Normal and Abnormal 2. Normal and Abnormal	1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing
URINE PREGNANCY/hCG*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID INFLUENZA A/B*	Positive and Negative	According to manufacturer's instructions
RAPID COVID-19*	Positive and Negative	Each new lot, new shipment, and new employee.
RAPID SYPHILIS*	Positive and Negative	Each day of testing
RSV*	Written procedure and proper training	According to manufacturer's instructions
AMINE	Written procedure and proper training	

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AREA D

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	QC REQUIREMENTS	QC FREQUENCY
URINE MICROSCOPY	Abnormal	Each week of testing; more frequently if required by manufacturer
MTM MEDIA	1. Check sterility 2. Observe condition	1. Each lot and shipment 2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	1. Positive and Negative 2. Positive and Negative	1. Each day of use 2. Each week of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS SEROLOGY	1. Reactive, WR, and NR 2. Needle 3. Rotator speed 4. Room temperature 5. Timer	1. Each day of testing 2. Once per vial of antigen, each new needle 3. Each day of testing 4. Each day of testing (and each batch) 5. Once per month with patient testing
WAIVED PROCEDURES		
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A_{1c}	2 Levels	Each new lot, new shipment, new employee, at least monthly with patient testing
URINE DIPSTICK: 1. Visual/Manual Method 2. Automated	1. Normal and Abnormal 2. Normal and Abnormal	1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing
URINE PREGNANCY/hCG*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID INFLUENZA A/B*	Positive and Negative	According to manufacturer's instructions
RAPID COVID-19*	Positive and Negative	Each new lot, new shipment, and new employee.
FECAL OCCULT BLOOD*	Written procedure and proper training	According to manufacturer's instructions
AMINE	Written procedure and proper training	

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

AREA E

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	QC REQUIREMENTS	QC FREQUENCY
URINE MICROSCOPY	<i>Abnormal</i>	<i>Each week of testing; more frequently if required by manufacturer</i>
MTM MEDIA	1. Check sterility 2. Observe condition	1. Each lot and shipment 2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	1. Positive and Negative 2. Positive and Negative	1. Each day of use 2. Each week of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS CARD TEST	1. <i>Reactive, WR, and NR</i> 2. <i>Needle</i> 3. <i>Rotator speed</i> 4. <i>Room temperature</i> 5. <i>Timer</i>	1. <i>Each day of testing</i> 2. <i>Once per vial of antigen, each new needle</i> 3. <i>Each day of testing</i> 4. <i>Each day of testing (and each batch)</i> 5. <i>Once per month with patient testing</i>
WAIVED PROCEDURES		
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A_{1c}	2 Levels	<i>Each new lot, new shipment, new employee, at least monthly with patient testing</i>
URINE DIPSTICK: 1. Visual/Manual Method	Normal and Abnormal	Each week of testing and with each new can of strips
2. Automated	<i>Normal and Abnormal</i>	<i>According to manufacturer's instructions, at least weekly with patient testing</i>
URINE PREGNANCY/hCG*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID INFLUENZA A/B*	Positive and Negative	According to manufacturer's instructions
RAPID COVID-19*	Positive and Negative	Each new lot, new shipment, and new employee.
RAPID SYPHILIS*	<i>Positive and Negative</i>	<i>Each day of testing</i>
FECAL OCCULT BLOOD*	Written procedure and proper training	According to manufacturer's instructions
AMINE	Written procedure and proper training	

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