2023 Quality Control Requirements

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
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.

2023 Quality Control Requirements

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
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.

2023 Quality Control Requirements

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 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	1. Normal and Abnormal	1. Each **week** of testing and with each new can of strips
2. Automated	2. Normal and Abnormal	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.

2023 Quality Control Requirements

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**
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
URINE DIPSTICK: **Visual/Manual Method**	Normal and Abnormal	Each **week** of testing and with each new can of strips
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 HIV*	Positive and Negative	According to manufacturer's instructions
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.