2018 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
GC-LECT 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 count 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	

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

2018 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
GC-LECT 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 count 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**
CHOLESTEROL, TOTAL	2 Levels	Each new lot and new shipment
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
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.

2018 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
GC-LECT 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 count 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	

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

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
GC-LECT 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 count 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	

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