2016 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: **1. DCA 2000 (and Vantage)** **2. Afinion AS100**	1. 2 Levels; 1 Level (alternating) 2. 2 Levels	1. Each new lot #; at least monthly with patient testing 2. Each new lot, new shipment, new employee, and at least every 30 days
URINE DIPSTICK: **1. Visual/Manual Method** **2. Automated** **3. Automated** (Clinitek Status, McKesson 120)	1. Abnormal only 2. Normal and Abnormal 3. Normal and Abnormal	1. Each **week** of testing, and with each new can of strips 2. Each **day** of testing, and with each new can of strips 3. 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
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 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 day of testing
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A_1c: **1. DCA 2000 (and Vantage)** **2. Afinion AS100**	 1. 2 Levels; 1 Level (alternating) 2. 2 Levels	 1. Each new lot #; at least monthly with patient testing 2. Each new lot, new shipment, new employee, and at least every 30 days
URINE DIPSTICK: **1. Visual/Manual Method** **2. Automated** **3. Automated** (Clinitek Status, McKesson 120)	 1. Abnormal only 2. Normal and Abnormal 3. Normal and Abnormal	 1. Each **week** of testing, and with each new can of strips 2. Each **day** of testing, and with each new can of strips 3. 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*
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
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
URINE COLONY COUNT	1. Check sterility of media ***2. Perform media quality control testing*** 3. Observe condition of media	1. Each lot and shipment *2. Each new lot number and/or shipment according to manufacturer's instructions* 3. Each shipment and each plate at time of use
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: **1. DCA 2000 (and Vantage)** **2. Afinion AS100**	 1. 2 Levels; 1 Level (alternating) 2. 2 Levels	 1. Each new lot #; at least monthly with patient testing 2. Each new lot, new shipment, new employee, and at least every 30 days
URINE DIPSTICK: **1. Visual/Manual Method** **2. Automated** **3. Automated** (Clinitek Status, McKesson 120)	 1. Abnormal only 2. Normal and Abnormal 3. Normal and Abnormal	 1. Each **week** of testing, and with each new can of strips 2. Each **day** of testing, and with each new can of strips 3. 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
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.

2016 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
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
PT/INR	TBD	TBD
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A_1c: **1. DCA 2000 (and Vantage)** **2. Afinion AS100**	1. 2 Levels; 1 Level (alternating) 2. 2 Levels	1. Each new lot #; at least monthly with patient testing 2. Each new lot, new shipment, new employee, and at least every 30 days
URINE DIPSTICK: **1. Visual/Manual Method** **2. Automated** **3. Automated** (Clinitek Status, McKesson 120)	1. Abnormal only 2. Normal and Abnormal 3. Normal and Abnormal	1. Each **week** of testing, and with each new can of strips 2. Each **day** of testing, and with each new can of strips 3. 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
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.