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

### 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	<ol> <li>Check sterility</li> <li>Observe condition</li> </ol>	<ol> <li>Each lot and shipment</li> <li>Each shipment and each plate at time of use</li> </ol>
GC TESTING: 1. Oxidase 2. Gram Stain	<ol> <li>Positive and Negative</li> <li>Positive and Negative</li> </ol>	<ol> <li>Each <u>day</u> of use</li> <li>Each <u>week</u> of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer</li> </ol>
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
	WAIVED PROC	EDURES
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A <sub>1</sub> c	2 Levels	Each new lot, new shipment, new employee, at least monthly with patient testing
URINE DIPSTICK 1. Visual/Manual Method	<ol> <li>Normal and Abnormal</li> <li>Normal and Abnormal</li> </ol>	<ol> <li>Each <u>week</u> of testing and with each new can of strips</li> <li>According to manufacturer's instructions, at</li> </ol>
2. Automated		least weekly with patient testing
URINE PREGNANCY/hCG* RAPID GROUP A STREP*	Positive and Negative	According to manufacturer's instructions
RAPID GROUP A STREP^ RAPID INFLUENZA A/B*	Positive and Negative Positive and Negative	According to manufacturer's instructions According to manufacturer's instructions
RAPID INFLUENZA A/B* 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	

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

#### 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
	1. Check sterility	1. Each lot and shipment
MTM MEDIA	2. Observe condition	2. Each shipment and each plate at time of use
GC TESTING: 1. Oxidase 2. Gram Stain	<ol> <li>Positive and Negative</li> <li>Positive and Negative</li> </ol>	<ol> <li>Each <u>day</u> of use</li> <li>Each <u>week</u> of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer</li> </ol>
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS SEROLOGY	1. Reactive, WR, and NR	1. Each <u>day</u> of testing
	2. Needle	2. Once per vial of antigen, each new needle
	3. Rotator speed	3. Each day of testing
	4. Room temperature	4. Each day of testing (and each batch)
	5. Timer	5. Once per month with patient testing
	WAIVED PROCED	OURES
TEST	QC REQUIREMENTS	QC FREQUENCY
GLUCOSE	2 Levels	Each day of testing
HEMOGLOBIN	2 Levels	Each day of testing
HEMOGLOBIN A <sub>1</sub> c	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 <u>week</u> 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
<b>RAPID GROUP A STREP*</b>	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
	training	

#### 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	Abnormal	Each week of testing; more frequently if required by manufacturer
MTM MEDIA	<ol> <li>Check sterility</li> <li>Observe condition</li> </ol>	<ol> <li>Each lot and shipment</li> <li>Each shipment and each plate at time of use</li> </ol>
GC TESTING: 1. Oxidase 2. Gram Stain	<ol> <li>Positive and Negative</li> <li>Positive and Negative</li> </ol>	<ol> <li>Each <u>day</u> of use</li> <li>Each <u>week</u> of testing; at least monthly if no patient testing is performed; more frequently if required by stain manufacturer</li> </ol>
WET MOUNT	Written procedure and proper training	Parallel testing with all assigned testing personnel twice per year
SYPHILIS CARD TEST	<ol> <li>Reactive, WR, and NR</li> <li>Needle</li> <li>Rotator speed</li> <li>Room temperature</li> <li>Timer</li> </ol>	<ol> <li>Each <u>day</u> of testing</li> <li>Once per vial of antigen, each new needle</li> <li>Each day of testing</li> <li>Each day of testing (and each batch)</li> <li>Once per month with patient testing</li> </ol>
	WAIVED PROCED	URES
meom		
TEST	QC REQUIREMENTS	<b>QC FREQUENCY</b>
GLUCOSE	2 Levels	QC FREQUENCY Each day of testing
GLUCOSE	2 Levels	Each day of testing
GLUCOSE HEMOGLOBIN	2 Levels 2 Levels	Each day of testing Each day of testing Each new lot, new shipment, new employee, at
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK:	2 Levels 2 Levels 2 Levels	Each day of testing Each day of testing Each new lot, new shipment, new employee, at least monthly with patient testing Each <b>week</b> of testing and with each new can of
GLUCOSEHEMOGLOBINHEMOGLOBIN A1cURINE DIPSTICK:1. Visual/Manual Method	2 Levels 2 Levels 2 Levels Normal and Abnormal	Each day of testing         Each day of testing         Each new lot, new shipment, new employee, at least monthly with patient testing         Each week of testing and with each new can of strips         According to manufacturer's instructions, at
GLUCOSE         HEMOGLOBIN         HEMOGLOBIN A <sub>1</sub> c         URINE DIPSTICK:         1. Visual/Manual Method         2. Automated	2 Levels 2 Levels 2 Levels Normal and Abnormal Normal and Abnormal	Each day of testingEach day of testingEach new lot, new shipment, new employee, at least monthly with patient testingEach week of testing and with each new can of stripsAccording to manufacturer's instructions, at least weekly with patient testing
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK: 1. Visual/Manual Method 2. Automated URINE PREGNANCY/hCG*	2 Levels 2 Levels 2 Levels Normal and Abnormal Normal and Abnormal Positive and Negative	Each day of testingEach day of testingEach new lot, new shipment, new employee, at least monthly with patient testingEach weekof testing and with each new can of stripsAccording to manufacturer's instructions, at least weekly with patient testingAccording to manufacturer's instructionsAccording to manufacturer's instructions
GLUCOSEHEMOGLOBINHEMOGLOBIN A1cURINE DIPSTICK:1. Visual/Manual Method2. AutomatedURINE PREGNANCY/hCG*RAPID GROUP A STREP*	2 Levels 2 Levels 2 Levels Normal and Abnormal Normal and Abnormal Positive and Negative Positive and Negative	Each day of testingEach day of testingEach day of testingEach new lot, new shipment, new employee, at least monthly with patient testingEach week of testing and with each new can of stripsAccording to manufacturer's instructions, at least weekly with patient testingAccording to manufacturer's instructions According to manufacturer's instructionsAccording to manufacturer's instructions
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK: 1. Visual/Manual Method 2. Automated URINE PREGNANCY/hCG* RAPID GROUP A STREP* RAPID INFLUENZA A/B*	2 Levels 2 Levels 2 Levels Normal and Abnormal Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative	Each day of testingEach day of testingEach new lot, new shipment, new employee, at least monthly with patient testingEach weekof testing and with each new can of stripsAccording to manufacturer's instructions, at least weekly with patient testingAccording to manufacturer's instructions According to manufacturer's instructionsAccording to manufacturer's instructions According to manufacturer's instructionsAccording to manufacturer's instructionsEach new lot, new shipment, and new
GLUCOSEHEMOGLOBINHEMOGLOBIN A_1cURINE DIPSTICK:1. Visual/Manual Method2. AutomatedURINE PREGNANCY/hCG*RAPID GROUP A STREP*RAPID INFLUENZA A/B*RAPID COVID-19*	2 Levels 2 Levels 2 Levels Normal and Abnormal Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative Positive and Negative Positive and Negative	Each day of testingEach day of testingEach day of testingEach new lot, new shipment, new employee, at least monthly with patient testingEach weekof testing and with each new can of stripsAccording to manufacturer's instructions, at least weekly with patient testingAccording to manufacturer's instructions According to manufacturer's instructionsAccording to manufacturer's instructions According to manufacturer's instructionsAccording to manufacturer's instructions Each new lot, new shipment, and new employee.