## **AREA A**

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 PROCEDURES			
TEST	QC REQUIREMENTS	QC FREQUENCY		
	<b>*</b> • • • • • • • • • • • • • • • • • • •	QUI INEQUENTOI		
GLUCOSE	2 Levels	Each day of testing		
GLUCOSE HEMOGLOBIN				
	2 Levels	Each day of testing		
HEMOGLOBIN	2 Levels 2 Levels	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at		
HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK  1. Visual/Manual Method	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal	Each day of testing  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips		
HEMOGLOBIN  HEMOGLOBIN A <sub>1</sub> c  URINE DIPSTICK  1. Visual/Manual Method  2. Automated	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing		
HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK  1. Visual/Manual Method 2. Automated URINE PREGNANCY/hCG*	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions		
HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> C URINE DIPSTICK  1. Visual/Manual Method  2. Automated URINE PREGNANCY/hCG* RAPID GROUP A STREP*	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions		
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 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions  According to manufacturer's instructions		
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* RAPID SYPHILIS*	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative Positive and Negative Written procedure and	Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions  According to manufacturer's instructions  Each day of testing		

<sup>\*</sup>Internal performance monitor result must be recorded for each patient.

# **AREA B**

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	Positive and Negative     Positive and Negative	<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 PROCI	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	
<ul><li>URINE DIPSTICK</li><li>1. Visual/Manual Method</li><li>2. Automated</li></ul>	<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 least weekly with patient testing</li> </ol>	
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	
	Written procedure and		

<sup>\*</sup>Internal performance monitor result must be recorded for each patient.

## **AREA C**

	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	Positive and Negative     Positive and Negative	<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	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			
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.			
KAI ID COVID-19					
RAPID SYPHILIS*	Positive and Negative	Each day of testing			
· ·	Positive and Negative Written procedure and proper training	Each day of testing  According to manufacturer's instructions			

<sup>\*</sup>Internal performance monitor result must be recorded for each patient.

## **AREA D**

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	
WIIWI WIEDIA	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	
TEST	QC REQUIREMENTS 2 Levels		
		QC FREQUENCY	
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c	2 Levels	QC FREQUENCY Each day of testing	
GLUCOSE HEMOGLOBIN	2 Levels 2 Levels	QC FREQUENCY  Each day of testing  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips	
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> C URINE DIPSTICK:	2 Levels 2 Levels 2 Levels	QC FREQUENCY  Each day of testing  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can	
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 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative	QC FREQUENCY  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips  2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions	
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> c URINE DIPSTICK: 1. Visual/Manual Method 2. Automated	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative	QC FREQUENCY  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips  2. According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions	
GLUCOSE HEMOGLOBIN HEMOGLOBIN A <sub>1</sub> C URINE DIPSTICK: 1. Visual/Manual Method 2. Automated URINE PREGNANCY/hCG*	2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative	Each day of testing Each day of testing Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing According to manufacturer's instructions According to manufacturer's instructions According 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*	2 Levels 2 Levels 2 Levels 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative	QC FREQUENCY  Each day of testing  Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips  2. According to manufacturer's instructions, at least weekly with patient testing  According 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 1. Normal and Abnormal 2. Normal and Abnormal Positive and Negative Positive and Negative Positive and Negative	Each day of testing Each day of testing Each new lot, new shipment, new employee, at least monthly with patient testing  1. Each week of testing and with each new can of strips 2. According to manufacturer's instructions, at least weekly with patient testing According to manufacturer's instructions According to manufacturer's instructions According to manufacturer's instructions Each new lot, new shipment, and new	

<sup>\*</sup>Internal performance monitor result must be recorded for each patient.

## **AREA E**

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	
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 Levels  Normal and Abnormal		
URINE DIPSTICK:		least monthly with patient testing  Each week of testing and with each new can of	
URINE DIPSTICK:  1. Visual/Manual Method	Normal and Abnormal	Each week of testing and with each new can of strips  According to manufacturer's instructions, at	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated	Normal and Abnormal  Normal and Abnormal	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated  URINE PREGNANCY/hCG*	Normal and Abnormal  Normal and Abnormal  Positive and Negative	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated  URINE PREGNANCY/hCG* RAPID GROUP A STREP*	Normal and Abnormal  Normal and Abnormal  Positive and Negative  Positive and Negative	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated  URINE PREGNANCY/hCG*  RAPID GROUP A STREP*  RAPID INFLUENZA A/B*	Normal and Abnormal  Normal and Abnormal  Positive and Negative  Positive and Negative  Positive and Negative	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions  According to manufacturer's instructions  Each new lot, new shipment, and new	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated  URINE PREGNANCY/hCG*  RAPID GROUP A STREP*  RAPID INFLUENZA A/B*  RAPID COVID-19*	Normal and Abnormal  Normal and Abnormal  Positive and Negative  Positive and Negative  Positive and Negative  Positive and Negative	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions  According to manufacturer's instructions  Each new lot, new shipment, and new employee.	
URINE DIPSTICK:  1. Visual/Manual Method  2. Automated  URINE PREGNANCY/hCG* RAPID GROUP A STREP* RAPID INFLUENZA A/B* RAPID COVID-19*  RAPID SYPHILIS*	Normal and Abnormal  Normal and Abnormal  Positive and Negative  Written procedure and proper	Each week of testing and with each new can of strips  According to manufacturer's instructions, at least weekly with patient testing  According to manufacturer's instructions  According to manufacturer's instructions  According to manufacturer's instructions  Each new lot, new shipment, and new employee.  Each day of testing	

<sup>\*</sup>Internal performance monitor result must be recorded for each patient.