510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K252619

B Applicant

QSTag Inc.

C Proprietary and Established Names

QSCHECK UISACR

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JFY	Class II	21 CFR 862.1225 - Creatinine Test System	CH - Clinical Chemistry
JIR	Class I	21 CFR 862.1645 - Urinary protein or albumin (nonquantitative) test system	CH - Clinical Chemistry
KQO	Class I	21 CFR 862.2900 - Automated urinalysis system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Microalbumin and creatinine in urine

C Type of Test:

Semi-quantitative urinalysis

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

QSCHECK UISACR is intended for the in vitro semi-quantitative measurement of the following parameters: microalbumin and creatinine in urine specimens and for Albumin/Creatinine ratio (ACR) calculated using those values. The results may be used in conjunction with clinical evaluation as an aid in the assessment for kidney function. The system is intended for prescription use only, in clinical laboratory settings.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only
QSCHECK UISACR is limited to clinical laboratory settings.

D Special Instrument Requirements:

Apple iPhone 14 (iOS v26) or Samsung Galaxy S23 (Android v16)

IV Device/System Characteristics:

A Device Description:

QSCHECK UISACR is provided as a kit that consists of:

- Single use test strips. Each test strip contains a minimum of 0.1 mg phenolsulfonphthalein and 30 mg citric acid for microalbumin and a minimum of 0.3 mg picric acid and 20 mg boric acid for creatinine.
- Instructions for use.
- QSCHECK-app smartphone application that runs on a dedicated smartphone (i.e., Apple iPhone 14 (iOS v26), Samsung Galaxy S23 (Android v16)). The test strip must be read only by the QSCHECK-app. The device does not include any tools for visual interpretation.
- Desiccant.

B Principle of Operation:

QSCHECK UISACR urine test strips contain a reagent pad with enzymes and chemicals that change color based on the concentration of each biomarker in the urine. The microalbumin test is based on affinity binding of albumin to a sulfonphthalein dye at a constant pH to develop a color ranging from pale green to aqua blue. The creatinine test is based on the reaction of creatinine with a dye-metal complex under an alkaline condition to form a purplish brown color complex. After completion of the reaction on the test strip, the QSCHECK-app smartphone application photographs and analyzes the degree of the color change, which are matched to microalbumin and creatinine values that are provided by the app.

C Instrument Description Information:

1. Instrument Name:

   Apple iPhone 14 (iOS v26) or Samsung Galaxy S23 (Android v16)

2. Specimen Identification:

   The QSCHECK-app will instruct the user to enter their patient identification information in the application.

3. Specimen Sampling and Handling:

   The test is performed using a urine sample collected in a urine cup.

4. Calibration:

   The QSCHECK-app performs automatic calibration during the analysis process for each measurement. User calibration is not required.

5. Quality Control:

   No external quality controls are provided. The use of commercially available quality control material is recommended.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ACR | LAB Urine Analysis Test System

B Predicate 510(k) Number(s):

K182384

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252619	K182384
Device Trade Name	QSCHECK UISACR	ACR | LAB Urine Analysis Test System
General Device Characteristic Similarities		
Intended Use	Intended for the measurement of microalbumin and creatinine in urine	Same
Sample Type	Human urine	Same
General Device Characteristic Differences		
Reader	Dedicated Apple iPhone 14 (iOS v26) or Samsung Galaxy S23 (Android v16)	Dedicated Apple iPhone 7 (iOS 12.0)

VI Standards/Guidance Documents Referenced:

- Clinical and Laboratory Standards Institute (CLSI) EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline, Third Edition.
- CLSI EP07, 3rd Edition: Interference Testing in Clinical Chemistry.
- CLSI EP09c, 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples.
- CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition.
- CLSI EP15-A3: User Verification of Precision and Estimation of Bias; Approved Guideline – Third Edition.
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.
- CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.
- CLSI GP16-A3: Urinalysis; Approved Guideline – Third Edition.
- ISO 17511, 2nd Edition: In vitro diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.
- ISO 14971, 3rd Edition: Medical Devices – Application of Risk Management to Medical Devices.
- IEC 62304, Edition 1.1: Medical Device Software – Software Life Cycle Processes.
- FDA guidance, “General Principles of Software Validation” issued on January 11, 2002.
- FDA Guidance, “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023.
- FDA Guidance, “Postmarket Management of Cybersecurity in Medical Devices” issued on December 28, 2016.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Single-site Precision

Precision testing was conducted at a single site using one Apple iPhone 14 (iOS v26) smartphone and one Samsung Galaxy S23 (Android v16) smartphone by one operator with a single test strip lot. Testing was conducted using human urine spiked with albumin and creatinine at the following concentrations: Sample 1 (~1.4 mg/dL albumin, ~213 mg/dL creatinine), Sample 2 (~8.0 mg/dL albumin, ~115 mg/dL creatinine), and Sample 3 (~15.9 mg/dL albumin, ~13.7 mg/dL creatinine). For within-run precision, each sample was tested in replicates of twenty in a single run over a single day. For between-run precision, each sample was tested in replicates of ten per run with two runs per day, over a single day. For between-day precision, each sample was tested in replicates of four per run with one run per day, over five days. The results are summarized in the tables below.

Apple iPhone 14 (iOS v26)

Microalbumin							
		Within-Run		Between-Run		Between-Day	
Sample level (mg/dL)	Measuring Block (mg/dL)	N	Exact Match Rate (%)	N	Exact Match Rate (%)	N	Exact Match Rate (%)
1.4	1	20	100	20	100	20	100
8.0	8	20	100	20	100	20	100
15.9	15	20	100	20	100	20	100

Creatinine							
		Within-Run		Between-Run		Between-Day	
Sample level (mg/dL)	Measuring Block (mg/dL)	N	Exact Match Rate (%)	N	Exact Match Rate (%)	N	Exact Match Rate (%)
13.7	10	20	100	20	100	20	100
115	100	20	100	20	100	20	100
213	200	20	100	20	100	20	100

Samsung Galaxy S23 (Android v16)

Microalbumin							
		Within-Run		Between-Run		Between-Day	
Sample level (mg/dL)	Measuring Block (mg/dL)	N	Exact Match Rate (%)	N	Exact Match Rate (%)	N	Exact Match Rate (%)
1.4	1	20	100	20	100	20	100
8.0	8	20	100	20	100	20	100
15.9	15	20	100	20	100	20	100

Creatinine							
		Within-Run		Between-Run		Between-Day	
Sample level (mg/dL)	Measuring Block (mg/dL)	N	Exact Match Rate (%)	N	Exact Match Rate (%)	N	Exact Match Rate (%)
13.7	10	20	100	20	100	20	100
115	100	20	100	20	100	20	100
213	200	20	100	20	100	20	100

Reproducibility

Reproducibility testing was conducted at three sites using three Apple iPhone 14 (iOS v26) smartphone and three Samsung Galaxy S23 (Android v16) smartphones. Each site had one operator performing testing of three spiked urine samples (Sample 1: 1.6 mg/dL albumin, 219 mg/dL creatinine; Sample 2: 9.1 mg/dL albumin, 116 mg/dL creatinine; Sample 3: 17.4 mg/dL albumin, 16 mg/dL creatinine) with one Apple iPhone 14 and one Samsung Galaxy S23. Each sample was tested in replicates of five per run, one run per day over five days using three test strip lots for a total of 225 results per level across sites and lots per smartphone type. The results are summarized in the table below.

Apple iPhone 14 (iOS v26)

Sample	N	Microalbumin		Creatinine	
		Measuring Block (mg/dL)	Exact Match Rate (%)	Measuring Block (mg/dL)	Exact Match Rate (%)
1	225	1	100	200	100
2	225	8	100	100	100
3	225	15	100	10	100

Samsung Galaxy S23 (Android v16)

Sample	N	Microalbumin		Creatinine	
		Measuring Block (mg/dL)	Exact Match Rate (%)	Measuring Block (mg/dL)	Exact Match Rate (%)
1	225	1	100	200	100
2	225	8	100	100	100
3	225	15	100	10	100

2. Linearity:

The reportable range for each analyte was evaluated by measuring five levels of creatinine and albumin in human urine at the following expected concentrations: Level 1 (1.3 mg/dL albumin, 311 mg/dL creatinine), Level 2 (4.8 mg/dL albumin, 217 mg/dL creatinine), Level 3 (9.5 mg/dL albumin, 109 mg/dL creatinine), Level 4 (15.9 mg/dL albumin, 61 mg/dL creatinine), Level 5 (16.3 mg/dL albumin, 17 mg/dL creatinine). The study was conducted by three operators. Each operator tested one Apple iPhone 14 (iOS v26) and one Samsung Galaxy S23 (Android v16) using three test strip lots in replicates of ten per sample per lot for a total of 90 replicates per sample per smartphone type. The results of the study are shown below.

Apple iPhone 14 (iOS v26)

Sample	N	Microalbumin		Creatinine	
		Measuring Block (mg/dL)	Exact Match Rate (%)	Measuring Block (mg/dL)	Exact Match Rate (%)
1	90	1	100	300	100
2	90	3	100	200	100
3	90	8	100	100	100
4	90	15	100	50	100
5	90	15	100	10	100

Samsung Galaxy S23 (Android v16)

Sample	N	Microalbumin		Creatinine	
		Measuring Block (mg/dL)	Exact Match Rate (%)	Measuring Block (mg/dL)	Exact Match Rate (%)
1	90	1	100	300	100
2	90	3	100	200	100
3	90	8	100	100	100
4	90	15	100	50	100
5	90	15	100	10	100

3. Analytical Specificity/Interference:

The analytical specificity of the QSCHECK UISACR was assessed using spiked human urine samples at three levels: Level 1 (1.3 mg/dL microalbumin, 211 mg/dL creatinine), Level 2

(8.6 mg/dL microalbumin, 114 mg/dL creatinine) and Level 3 (20.9 mg/dL microalbumin, 14 mg/dL creatinine). Each level sample was further divided into two aliquots: control (with no added interferent) and test (with added interferent). Each sample was measured in replicates of ten using one lot of test strip on Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android v16).

The results of the test sample with potentially interfering substance were compared to the results of the control sample. No interference was defined as 100% agreement between test and control samples. Interference was defined as a change in output of one or more color blocks between test and control samples. When interference was observed, dose response testing was performed to identify the lowest concentration at which interference was observed.

The substances at the concentrations listed in the table below were found not to interfere with microalbumin, creatinine and ACR.

Substance	Highest concentration of substance at which no interference was observed (mg/dL unless otherwise indicated)
Acetaminophen	300
Albumin (only creatinine was tested as the measurand)	880
Ascorbic acid	220
Bilirubin	6
Caffeine	37
Blood	0.05%
Calcium Chloride	210
Captopril	12
Citric Acid	100
Creatinine (only microalbumin was tested as the measurand)	750
Cyanocobalamin (Vitamin B12)	0.16
Dapagliflozin	0.03
Fructose	100
Glucose	5000
Glycine	450
Hemoglobin	6.8
Hydrochlorothiazide	5
Hydroxychloroquine sulfate	8
Iron Sulfate	24
Acetoacetic Acid	300
Leukocytes	2500 leukocytes/µL
Losartan	5
Metformin Hydrochloride	285
Phenolphthalein	1060

Potassium Chloride	1990
Riboflavin	20
Sodium Acetate	260
Sodium Bicarbonate	975
Sodium Chloride	5100
Sodium Nitrite	9
Sodium-2-mercaptoethanesulfonate (Mesna)	562.5
Theophylline	100

The following tables show the substances that interfered with the proposed device. Results are expressed as the lowest concentration of the substance that exhibits interference and the resulting change in color block output.

Albumin

Interferent	Lowest concentration interference was observed (mg/dL)	Analyte level (mg/dL)	Effect on results	
			iPhone 14	Galaxy S23
Sodium Bicarbonate	1300	1	Falsely elevated by one color block	Falsely elevated by one color block
		8	Falsely elevated by one color block	Falsely elevated by one color block
		15	No change	No change
Sodium-2-mercaptoethanesulfonate (Mesna)	750	1	Falsely elevated by one color block	Falsely elevated by one color block
		8	Falsely elevated by one color block	Falsely elevated by one color block
		15	No change	No change

Creatinine

Interferent	Lowest concentration interference was observed (mg/dL)	Analyte level (mg/dL)	Effect on results	
			iPhone 14	Galaxy S23
Ascorbic acid	330	200	No change	Falsely decreased by one color block
		100	Falsely decreased by one color block	Falsely decreased by one color block
		10	No change	No change
Sodium Bicarbonate	1300	200	Falsely decreased by one color block	Falsely decreased by one color block
		100	Falsely decreased by one color block	Falsely decreased by one color block
		10	No change	No change

Sodium-2-mercaptoethanesulfonate (Mesna)	750	200	Falsely decreased by one color block	Falsely decreased by one color block
		100	Falsely decreased by one color block	Falsely decreased by one color block
		10	No change	No change

Specific gravity
Human urine samples spiked with albumin and creatinine (Level 1: 1.6 mg/dL albumin, 221 mg/dL creatinine; Level 2: 7.9 mg/dL albumin, 127 mg/dL creatinine; Level 3: 16.9 mg/dL albumin, 19 mg/dL creatinine) were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035, and 1.040 and tested. No interference from specific gravity was detected for albumin or creatinine measurement in the examined range on both Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android v16).

pH
Human urine samples spiked with albumin and creatinine (Level 1: 1.6 mg/dL albumin, 221 mg/dL creatinine; Level 2: 7.9 mg/dL albumin, 127 mg/dL creatinine; Level 3: 16.9 mg/dL albumin, 19 mg/dL creatinine) were adjusted to pHs of 4, 5, 6, 7, 8, and 9 and tested. No interference from pH was detected for albumin or creatinine measurement in the examined range on both Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android v16).

4. Assay Reportable Range:

The reportable values for microalbumin are 1, 3, 8, and 15 mg/dL and for creatinine are 10, 50, 100, 200 and 300 mg/dL. The reportable values for ACR are Normal (ACR < 30 mg albumin/g creatinine), Abnormal (30-300 mg albumin/g creatinine) and Very Abnormal (> 300 mg albumin/g creatinine).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability
Traceability is established using an internal control material.

Sample stability
Sample stability testing was conducted with twenty native human urine samples that were stored under various storage conditions. QSCHECK UISACR urine test strips with Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android v16) smartphones were used to test samples at baseline and after storage. The sample stability results support the labeling claim that if the test is not performed immediately, samples may be stored in a freezer at -20°C for up to 3 weeks.

6. Detection Limit:

A limit of detection study was conducted to determine the cutoff points for every color block for both microalbumin and creatinine. Human urine samples spiked with microalbumin (0.7 to 22.3 mg/dL) or creatinine (3 to 334 mg/dL) were tested using three test strip lots and ten replicates per lot using one Apple iPhone 14 (iOS v26) smartphone and one Samsung Galaxy S23 (Android v16) smartphone. The cutoff for each color block is defined as the lowest

concentration of analyte at which over 50% of the test results were positive for each measuring block. The results are shown below.

Apple iPhone 14 (iOS v26)

Microalbumin			Creatinine		
Color Block (mg/dL)	Cut off Value (mg/dL)	Match Rate (%)	Color Block (mg/dL)	Cut off Value (mg/dL)	Match Rate (%)
1	0.7	100%	10	3	100%
3	2.6	63.3%	50	47	83.3%
8	6.6	83.3%	100	82	86.7%
15	12.3	63.3%	200	188	63.3%
			300	281	60.0%

Samsung Galaxy S23 (Android v16)

Microalbumin			Creatinine		
Color Block (mg/dL)	Cut off Value (mg/dL)	Match Rate (%)	Color Block (mg/dL)	Cut off Value (mg/dL)	Match Rate (%)
1	0.7	100%	10	3	100%
3	2.6	56.7%	50	47	80.0%
8	6.6	80.0%	100	82	83.3%
15	12.3	66.7%	200	188	70.0%
			300	281	56.7%

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   See Section VII.B.1. Method Comparison.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was performed at three clinical sites with 300 unique urine samples (100 samples per site) from microalbuminuria patients by one operator. The results from the QSCHECK UISACR were compared to the results from an FDA cleared comparator device. No altered samples were used in this study. The microalbumin, creatinine, and ACR results for Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android OS v16) smartphones, for combined sites, is shown below.

Apple iPhone 14 (iOS v26)

Albumin	Reported blocks (mg/dL)	Comparator device				Total n
		1	3	8	15	
QSCHECK UISACR	1	69 (90.8%)	3 (4.4%)	0	0	72
	3	7 (9.2%)	59 (86.8%)	4 (5.6%)	0	70
	8	0	6 (8.8%)	63 (88.7%)	7 (8.2%)	76
	15	0	0	4 (5.6%)	78 (91.8%)	82
Total n		76	68	71	85	300
% Exact agreement		90.8%	86.8%	88.7%	91.8%	89.5%
% Within one block		100%	100%	100%	100%	100%

Creatinine	Reported blocks (mg/dL)	Comparator device					Total n
		10	50	100	200	300	
QSCHECK UISACR	10	66 (91.7%)	6 (10.9%)	0	0	0	72
	50	6 (8.3%)	48 (87.3%)	2 (3.9%)	0	0	56
	100	0	1 (1.8%)	44 (86.3%)	2 (3.7%)	0	47
	200	0	0	5 (9.8%)	50 (92.6%)	7 (10.3%)	62
	300	0	0	0	2 (3.7%)	61 (89.7%)	63
Total n		72	55	51	54	68	300
% Exact agreement		91.7%	87.3%	86.3%	92.6%	89.7%	89.5%
% Within one block		100%	100%	100%	100%	100%	100%

ACR	Reported result	Comparator device			
		Normal	Abnormal	Very Abnormal	Total n
QSCHECK UISACR	Normal	101 (92.7%)	8 (5.6%)	0	109
	Abnormal	8 (7.3%)	128 (89.5%)	5 (10.4%)	141
	Very Abnormal	0	7 (4.9%)	43 (89.6%)	50
Total n		109	143	48	300
% Exact agreement		92.7%	89.5%	89.6%	90.6%
% Within one block		100%	100%	100%	100%

Samsung Galaxy S23 (Android v16)

Albumin	Reported blocks (mg/dL)	Comparator device				Total n
		1	3	8	15	
QSCHECK UISACR	1	68 (89.5%)	3 (4.4%)	0	0	71
	3	8 (10.5%)	61 (89.7%)	4 (5.6%)	0	73
	8	0	4 (5.9%)	63 (88.7%)	8 (9.4%)	75
	15	0	0	4 (5.6%)	77 (90.6%)	81
Total n		76	68	71	85	300
% Exact agreement		89.5%	89.7%	88.7%	90.6%	89.6%
% Within one block		100%	100%	100%	100%	100%

Creatinine	Reported blocks (mg/dL)	Comparator device					Total n
		10	50	100	200	300	
QSCHECK UISACR	10	65 (90.3%)	5 (9.1%)	0	0	0	70
	50	7 (9.7%)	49 (89.1%)	3 (5.9%)	0	0	59
	100	0	1 (1.8%)	44 (86.3%)	2 (3.7%)	0	47
	200	0	0	4 (7.8%)	50 (92.6%)	7 (10.3%)	61
	300	0	0	0	2 (3.7%)	61 (89.7%)	63
Total n		72	55	51	54	68	300
% Exact agreement		90.3%	89.1%	86.3%	92.6%	89.7%	89.6%
% Within one block		100%	100%	100%	100%	100%	100%

ACR	Reported result	Comparator device			
		Normal	Abnormal	Very Abnormal	Total n
QSCHECK UISACR	Normal	101 (92.7%)	9 (6.3%)	0	110
	Abnormal	8 (7.3%)	129 (90.2%)	5 (10.4%)	142
	Very Abnormal	0	5 (3.5%)	43 (89.6%)	48
Total n		109	143	48	300
% Exact agreement		92.7%	90.2%	89.6%	90.8%
% Within one block		100%	100%	100%	100%

2. Matrix Comparison:

Not applicable. This test is only for use with urine samples.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The following statements regarding expected values are provided in the device labeling:

"The expected values for the QSCHECK UISACR are as follows:

Albumin: Albumin is normally present in urine at concentrations of less than 2 mg/dL.[1] Moderately increased albuminuria is defined as an albumin excretion rate of 30~299 mg/24 hours.[2,3]

Creatinine: Creatinine concentrations of 10-300 mg/dL are normally present in urine.

Albumin-to-Creatinine Ratio: Albumin is normally present in urine at concentrations of < 30 mg/g, where mg/g represents mg albumin per g creatinine. Moderately increased albuminuria is indicated at a ratio result of 30 - 300 mg/g and severely increased albuminuria at a ratio of > 300 mg/g.[4]"

References:

1. Burtis C.A.; and Ashwood ER.: Tietz Textbook of Clinical Chemistry 3rd ed. Philadelphia: Saunders; 1999;pp.483-484.
2. Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin-Dependent) Diabetic patients Without Renal Failure in Italy-Validation of Screening Techniques to Detect Microalbuminuria. Acta Diabetol. 29: 156-166; 1992.
3. American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.
4. Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.

F Other Supportive Instrument Performance Characteristics Data:

The sponsor conducted flex studies with human urine samples spiked with albumin and creatinine to three levels of albumin, creatinine and ACR. The expected results for the three levels of urine samples were 1 mg/dL, 8 mg/dL and 15 mg/dL for microalbumin; 10 mg/dL, 100 mg/dL and 200 mg/dL for creatinine; Normal, Abnormal, Very Abnormal for ACR. Each of the studies described below was conducted with one Apple iPhone 14 (iOSv26) and one Samsung Galaxy S23 (Android v16) using one lot of test strip. Each sample was tested on each phone in replicates of ten.

1. Dipping Time: This study was conducted to assess how test strip sampling times impact the accuracy of the QSCHECK-UISACR. Test strips were dipped in the urine samples for four different durations (1, 5, 10, or 30 seconds). The residual urine was immediately removed from the test strip and the assay time was held constant at 60 seconds. For both creatinine and albumin, the results support that a dipping time from 1 to 10 seconds does not impact test performance. The instructions for use and QSCHECK-app directs the professional user to dip the strip for 1 second to apply the sample. Users are warned that incorrect results may occur if the 1-second dipping time is not adhered to.

2. Reaction Time: This study was conducted to assess how the reaction time (between dipping the test strip in a urine sample and imaging the test strip) impacts the accuracy of QSCHECK-UISACR. Test strips were dipped in the urine samples for one second and the residual urine was immediately removed from the strip. The operator then waited a predetermined amount of time (30, 45, 60, 90 or 120 seconds) before imaging the test strip. For both creatinine and albumin, the results support that a reaction time from 45 to 90 seconds does not impact test performance. The instructions for use and QSCHECK-app directs the professional user to wait for 60 seconds to allow for the urine sample to react with the test strip prior to scanning the strip for analysis. Users are warned that incorrect results may occur if the 60-second reaction time is not adhered to.

3. Residual sample: This study was conducted to assess how the presence of residual sample on the test strip impacts the accuracy of QSCHECK-UISACR. For the condition without residual sample, test strips were dipped in samples for one second, the residual urine was immediately removed from the strip, and the strip was placed on a flat surface for 60 seconds to allow the reaction to occur. For the condition with residual sample, test strips were dipped in samples for 1 second and, without removing any residual urine, the test strip was then placed on a flat surface for 60 seconds to allow the reaction to occur. For both creatinine and albumin, the presence of residual sample impacted the accuracy of the test results on both iPhone 14 (iOS v26) and Galaxy S23 (Android v16). The instructions for use and QSCHECK-app directs the professional user to lightly tap the test strip on an absorbent surface to remove the residual urine. Users are warned that incorrect results may occur if residual specimen is not immediately removed after dipping the test strip in the urine.

4. Illumination intensity: This study was conducted to evaluate how environmental lighting conditions impact the accuracy of QSCHECK-UISACR. Test strips were dipped in each sample for one second, residual urine was immediately removed, and a 60-second reaction time was employed before imaging the test strip under different simulated light conditions (illumination intensities of 60-100 lx, 100-200 lx, 200-300 lx, 300-400 lx or 400-500 lx). For both creatinine and albumin, test performance was not impacted for any of the illumination

intensities tested. The instructions for use and QSCHECK-app describe that the test strip may need to be rescanned if the recommended lighting conditions (60x (a dimly lit laboratory) to 500 lx (typical laboratory lighting)) are not met. If lighting conditions fall outside this range, the QSCHECK-app will prompt the user to rescan the test strip (if the maximum 90-second reaction time frame has not been exceeded) or test using a new test strip (if the maximum 90-second reaction time frame has been exceeded).

5. Shadowing: This study was conducted to evaluate how shadows on the test strip impact the accuracy of QSCHECK-UISACR. Test strips were dipped in the urine test samples for one second, residual urine was immediately removed, and a 60-second reaction time was employed before imaging the test strip. Test strips were scanned under three different shadowing conditions: no shadow on the test strip, 25% area under shadow, and 50% area under shadow. For both creatinine and albumin, the results support that 0% to 25% shadowing does not impact the test performance. The instructions for use and QSCHECK-app describe that the test strip may need to be rescanned if more than 25% of the test strip's measurement area is covered by shadow. If more than 25% of the area of the test strip is covered by shadow, the QSCHECK-app will request a rescan of the test strip (if the maximum 90-second reaction time frame has not been exceeded) or test using a new test strip (if the maximum 90-second reaction time frame has been exceeded).

6. Scan Angles: This study was conducted to evaluate how the scan angle on the test strip impacts the accuracy of QSCHECK-UISACR. Test strips were dipped in each sample for one second, residual urine was immediately removed, and a 60-second reaction time was employed before imaging the test strip. Test strips were scanned at different angles (0°, 30°, or 60°). For both creatinine and albumin, the results support that a scan angle from 0° to 30° does not impact the test performance. The instructions for use and QSCHECK-app describe that the test strip may need to be rescanned if the scan angle is more than 30°. If the scan angle is more than 30°, the QSCHECK-app will request a rescan (if the maximum 90-second reaction time frame has not been exceeded) or test using a new test strip (if the maximum 90-second reaction time frame has been exceeded).

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.