



STANDARDIZED TESTING / OPERATING PROTOCOL REQUEST/ANNOUNCEMENT

iRICELL Complete Urinalysis System Go Live and UA Standardization

Description: Annie Penn, Moses Cone, Wesley Long, and Women's Hospital will go live will standardize urinalysis testing and Alamance and Greensboro/Reidsville laborate will standardize urinalysis testing and reporting procedures.	
Implementation Date:	12/05/17 at 0900
	Click on the boxes that apply:
	☐ Alamance Cancer Center
Donforming	⊠Annie Penn Hospital
Performing Locations:	⊠Med Center at Mebane
Locations.	⊠Med Center at High Point
	⊠Moses Cone Hospital
	⊠Wesley Long Hospital
	⊠Women's Hospital
	Click on the boxes that apply:
	☐ Alamance Cancer Center
	⊠Annie Penn Hospital
Affected Locations:	⊠Med Center at Mebane
	⊠Med Center at High Point
	⊠Moses Cone Hospital
	⊠Wesley Long Hospital
	⊠Women's Hospital

	Click on the boxes that apply:
Affected Departments:	□Blood Bank □Cytology □Flow Cytometry □Histology □Microbiology □Phlebotomy □Point of Care ⊠Rapid Response Lab □Respiratory Therapy □Specimen Processing
Specimen Type:	Urine collected in an acceptable urine container. NOTE: Specimens for iRICELL analysis must not be collected in Medegen urine cups with blue lid due to possible interference of silicate particles. Urine specimens received in these Medegen cups must be tested using an alternate method.
Updated Clinical Lab Procedures:	Alamance and Mebane: UA-700-Meb UA-702-Meb UABF-709-AR UA-702-AR UABF-708-AR Greensboro/Reidsville: UA-4522-CH Urinalysis Reporting Procedure UA-4551-CH Urinalysis Information Sheet UA-4510-CH Microscopic Examination of Urines UA-4505-CH Multistix Visual Method UA-4500-CH Testing of Routine Urinalysis Specimens and Operation of CLINITEK Atlas UA-4550-CH Testing of Routine Urinalysis Specimens and Operation of CLINITEK Advantus QM-1720C-XX Test Menu and Proficiency Testing Enrollment UA-4555- CH iRICELL Urinalysis Information Sheet *NEW* UA-4554-CH IRIS iQ200 Auto Particle Recognition (APR) Guide *NEW* UA-4556-CH Testing of Routine Urinalysis Specimens and Operation of the iChemVELOCITY *NEW* UA-4553-CH Testing of Routine Urinalysis Specimens and Operation of the iQ200 *NEW*
Retired Clinical Lab Procedures:	UA-4500-WL Testing of Routine Urinalysis Specimens and Operation of CLINITEK Atlas with Rack Sample Handler UA-4500L-WL Atlas Maintenance Log
Notification to Client:	Click on the boxes that apply: □ Section Not Applicable

	⊠Memo Needed
	Memo sent to Medical Staff on 12/01/2017
	Distribution of Memo:
	⊠Medical Staff
	□ Annie Penn (Primary Source Physicians)
	⊠ Dentist
	☑ Emergency Department/Urgent Care Centers
	☐ Family Practice
	☑ Infectious Docs #ID Docs
	(John Campbell, Robert Comer, Jeffrey Hatcher, Cynthia Snider, Kees Van Dam) ⊠ OB/GYN
	□ Pathology
	⊠ Pediatricians
	⊠ Psych
	⊠ Radiology
	⊠ Surgery
	☐ #Nursing Leadership (Directors, Asst. Directors, Clinical Nurse Manager)
	☐ Pharmacy - Send to DeAnne Brooks & Jim Hasspacher
	☐ #IM Residents
	☐ Kim Helsabeck
	☐ Phlebotomy Managers and Supervisors
	☐ Point of Care: Sheila, Kim & Marty
	Click on the boxes that apply:
	☐ Section Not Applicable
	⊠CAP Test menu change needed
	Added Urinalysis Microscopic Automated (2893) to the sites CAP Test Menu that are
	implementing the IRIS.
	Deleted Urinalysis dipstick Manual (waived) (2756) from applicable sites CAP Test
	Menu.
Accreditation	□CMS Analyte form change needed
Section:	☑Proficiency Testing surveys changes needed or orderedUrinalysis Microscopic Automated PT survey (UAA) ordered for 2018
	ICHEM instruments (CMP1) proficiency testing replaced CMP for 2018
	The IRIS will be our primary method so please run CAP proficiency testing on the
	IRIS.
	Please perform method comparison and alternate assessment PT on the following:
	Advantus to IRIS
	Manual microscopic to IRIS automated microscopic

	Click box and type needed	changes/additions:			
	☐ Section Not Applicable				
	⊠LIS changes				
	TEST CODE	CURRENT	NEW		
	Urinalysis Complete	UA- Greensboro/Reidsville UACOMP- Alamance	UACMP		
	Urine Microscopic	UMIC	UMICI		
Laboratory IT section:	Task List by each site, IT, a Sperm PRES in female UNCX (FAIL AUTO) Red/Blue AFCOL (FAIL AUTO) Red/Blue AFCOL (FAIL AUTO) BIOCH comment on a COLORLESS, STRAIN TP ≥ 300 mg/dL − Iri GLU ≥ 500 mg/dL − Iri Keyboard change for New Keyboard = UA Dipsticks Removal of RBCCL a Defaulting C-IRQCA iQ Controls: Adding it for Iris methods (IQ) Update ARMC and Members and Me	addition o mg/dL ctions been made and will be tested accound QA departments: le under 15 years (FAIL AUTOVER) VER) – Iris only AIL AUTOVER) – Iris only all urines with color other than YELI	- Iris only OW, al Dipsticks py Atlas, and Manual ual Microscopy SO/Reidsville) NEG and qualifying) , 2+ [Symbol] g/dL - All sites		

At 0900 on December 5th, 2017, the Cone Health laboratories will standardize urinalysis testing and reporting. Annie Penn, Moses Cone, Wesley Long, and Women's Hospital will go live with iRICELL Complete Urinalysis System testing.

All sites:

- Utilize new Sunquest UA keyboard to enter urinalysis results that are not autoverified.
- Perform conditional microscopic examination on UACMP and/or UMAC orders if positive protein, positive blood, positive leukocyte esterase, positive nitrite, and/or glucose >500mg/dL

Note: Orders placed for UACOMP (ARMC/Mebane) and UA (GSO/Reidsville) prior to go live will need to be credited and manually reordered as UACMP.

- Cease pathologist review if more than 15 renal tubular epithelial cells are seen per 10 high power fields.
- See attached documents IRIS Go Live Information Summary
- See attached Go Live Tasks

Technical Staff Update:

iRICELL sites only:

- Update site specific Rapid Response Lab Quality Control Chart, QM-1649 with iChemVELOCITY and iQ Control/Focus urinalysis control material if applicable.
- Record parallel testing of new lot reagents on Reagent Verification Log QM-1715F-CH.

Alamance:

- iRICELL analyzer settings should be updated with standardized gating and report format settings in AM of 12/05/17.
- Utilize TRICHM and USPRM test codes to report Trichomonas and Sperm PRESENT.

Greensboro/Reidsville:

Cease testing of supernatant from grossly bloody urines. For grossly bloody urines, report Color and Clarity results only in LIS and enter comment NRCI 'Test Not Performed due to Color Interference' for all other macroscopic results.

STOP Initiator:

Amy Younts- Meredith

IRIS- Go-Live information Summary

ALL SITES (Including Clinitek Users):

- Grossly Bloody Specimens-
 - Discontinue biochemical testing of supernatant
 - o Report only Color and Clarity only in LIS
 - Enter comment 'NRCI' (Test not performed due to color interference) for all other macroscopic results
- Urinalysis biochemical reporting format-

Analyte	IRIS Reporting Options	Clinitek Reporting Options	Multistix 10SG Manual Dipstick Reporting Options	
Specific Gravity	1.005-1.046 (Report >=1.046 as >1.046; Report <=1.005 as <1.005)	ADVANTUS & STATUS: 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 (Report <=1.005 as <1.005; Report >=1.030 as >1.030) ATLAS: AMR= 1.000-1.046 (Report >1.046 as >1.046)	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 (Report <=1.005 as <1.005; Report >=1.030 as >1.030) **Add 0.005 if pH >=6.5	
рН	Numeric 5.0, 6.0, 7.0, 8.0, 9.0	ADVANTUS & STATUS: 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, >9.0 ATLAS: Numeric	Numeric 5.0, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5	
Ketone	Neg, 5, 20, 80 mg/dL	Neg, 15, 40, >=80 mg/dL	Neg, 15, 40, >=80 mg/dL	
Bilirubin	Neg, Small, Mod	Neg, Small, Mod, Large	Neg, Small, Mod, Large	
Protein	Neg, 30, 100, >=500mg/dL (report as >=300mg/dL)	Neg, 30, 100, >=300mg/dL	Neg, 30, 100, >=300mg/dL	
Blood	Neg, Small, Mod, Large	Neg, Small, Mod, Large (report TRACE as SMALL)	Neg, Small, Mod, Large (report TRACE as SMALL)	
Nitrite	Neg or Pos	Neg or Pos	Neg or Pos	
Leukocyte Esterase	Neg, Trace, Small, Mod, Large	Neg, Trace, Small, Mod, Large	Neg, Trace, Small, Mod, Large	
Glucose	Neg, 50, 150, >=500mg/dL	Neg, 100, 250, 500, >=1000mg/dL (report >=1000mg/dL as >=500mg/dL)	Neg, 100, 250, 500, 1000, 2000mg/dL(report 1000mg/dL & 2000mg/dL as >=500mg/dL)	

- No path review required for > 15 renal tubular epithelial cells per 10hpf
- Report WBCCL (White Blood Cell Clumps) if PRESENT
- Report NSEPI (Non-Squamous Epithelial Cells) using semi-quantitative grading criteria
- Individual test codes made for each type of crystal & cast. These are reported as PRESENT. An exception to this is the presence of crystals not identified by the IRIS which are reported under CRYS test code as a canned comment: NH4U, HA, BIL, SUL, CHCRY
- Perform microscopic exam when Glucose >=500mg/dL
- Use 'UA keyboard in Sunquest for result entry

IRIS Users Only:

• Use 'UA' keyboard in Sunguest ONLY for non-autoverified result entry

Suspected QNS specimens should have biochemical testing performed using backup methodology to
determine if a microscopic exam is required. If a microscopic exam is required, perform microscopic
testing on the iQ200 or via manual microscopy. QNS specimens must be resulted manually in Sunquest
using the 'UA' keyboard.

Iris (Greensboro/Reidsville) Go Live Tasks

All of these tasks/items are in the Live (NC2) environment. Do not use TEST81 or TESTAR.

Please initial as these tasks/items are completed/verified.

Important Note:	If ordering a	test	patient	in NC2,	please	use	TEST-	to genera	te MRN

1.	Enter current lot of CA, CB, CC and IQ QC into Sunquest if not already present.				
2.	Perform QC.				
	□ Verify QC crosses into Sunquest.				
	□ Verify CA, CB, CC default to C-IRQCA, C-IRQCB, C-IRQCC.				
	 Verify ASCORA result is present for each level. 				
	 Verify C-IQPOS and C-IQNEG cross appropriately. 				
	Note: Remember you must change the Specimen ID from the NC or PC number to C-IQNEG or C-IQPOS				
3.	Perform Iris to Advantus and Iris to Manual Microscopic Instrument Comparison				
	□ Perform urinalysis and microscopic on five specimens on the Iris/Advantus/Manu				
	Microscopic.				
	□ Fill out QM-1517L?-CH Urinalysis Comparability of Methods Worksheet				
	□ Attach to blue <i>QM-1925F-CH</i> and obtain appropriate signatures.				
	□ File with Urinalysis Method Comparisons for 2017.				
	□ Also, attach comparison to purple/pink <i>QM-1525F-CH</i> and obtain appropriate				
	signatures.				
	□ File this with your 2017 Alternate Assessments.				
4.	In Live environment, order the following and record the accession number:				
	In lieu of manually ordering the below tests, you can use real patient orders. Just make				
	sure you record the applicable accession number.				
	□ UACMP: Accession□ UMAC: Accession *positive specimen				
	UMAC: Accession *positive specimen				
	UMAC: Accession *negative specimen				
_	UDIP: Accession				
5.	Analyze the above four samples on the Iris.				
	□ Verify UACMP performs microscopic.				
	□ Verify UMAC (positive specimen) performs microscopic.				
	□ Verify UMAC (negative specimen) does NOT perform microscopic.				
	□ Verify UDIP does NOT perform microscopic.				
	□ Save Iricell printouts for all four specimens and attach to this form.				
6	If printout does not automatically print, please request printed copy from Iricell. Verify BIOCH comment is automatically added in Sunquest for urines with colors other				
0.	than yellow, straw or colorless:				
	In lieu of manually ordering the below tests, you can use real patient orders. Just make				
	sure you record the applicable accession number.				
	, , , , , , , , , , , , , , , , , , , ,				

		UACMP: Accession
		UMAC: Accession
		UDIP: Accession
7.	Verify	examples of the following and record applicable accession number:
		Patient with glucose ≥ 500 mg/dL: Accession
		Patient with total protein ≥ 300 mg/dL: Accession
		Hint: Order a test patient and use CB as test material. This control has greater
		than values for both glucose and total protein.
8.	-	USPRM in female < 16 years old does not autofile in Sunquest.
		Order UACMP on 14 year old female: Accession
		Perform analysis and add USPRM to microscopic results.
		Release results to Sunquest.
		Report results in Sunquest.
		Attach copy of Iricell printout to this form.
9.	-	UCOL BLUE and RED do not autofile in Sunquest
		Order UDIP: Accession: (red)
		Order UDIP: Accession: (blue)
		Perform analysis and change colors to red or blue.
		Release results to Sunquest.
		Report results in Sunquest.
		Attach copy of Iricell printout to this form.
10	•	UNCX present does not autofile in Sunquest
		Order UACMP: Accession:
		Perform analysis and classify particle as UNCX.
		Release results to Sunquest.
		Report results in Sunquest.
		Attach copy of Iricell printout to this form.

Once completed, please scan and email this checklist and supporting documentation to Jackie Hobbins.

Status (MedCenter Mebane) Go Live Tasks

All of these tasks/items are in the Live (NC2) environment. Do not use TEST81 or TESTAR.

Please initial as these tasks/items are completed/verified.

Important Note: If ordering a test patient in NC2, please use TEST- to generate MRN

1.	In Live environment, order the following and record the accession number:					
	In lieu	ı of manually	ordering the below test	s, you can use real patient orders.	Just make	
	sure y	ou record the	e applicable accession	number.		
		UACMP:	Accession			
		UMAC:	Accession	*positive specimen		
		UMAC:	Accession	*negative specimen		
		UDIP:	Accession			
2.	Analy	ze the above	four samples on the Iri	S.		
		Verify UACI	IP performs microscop	ic.		
	 Verify UMAC (positive specimen) performs microscopic. 					
		Verify UMA	C (negative specimen)	does NOT perform microscopic.		
		Verify UDIP	does NOT perform mid	croscopic.		
		Save Status	printouts for all four sp	ecimens and attach to this form.		
3.	Verify	examples of	the following and reco	rd applicable accession number:		
			glucose ≥ 500 mg/dL:			
		Hint: Order	a test patient and use	positive control material.		

Advantus (MedCenter High Point) and Status (Alamance) Go Live Tasks

All of these tasks/items are in the Live (NC2) environment. Do not use TEST81 or TESTAR.

Please initial as these tasks/items are completed/verified.

Important Note: If ordering a test patient in NC2, please use TEST- to generate MRN

•	Verify examples of the following and record applicable accession number:				
	□ Patient with glucose ≥ 500 mg/dL: Accession				
	□ Save Advantus printout for specimen.				
	Hint: Order a test patient and use positive control material.				

Advantus (Wesley Long) Go Live Tasks

All of these tasks/items are in the Live (NC2) environment. Do not use TEST81 or TESTAR.

Please initial as these tasks/items are completed/verified.

Important Note: If ordering a test patient in NC2, please use TEST- to generate MRN

1.	In Live environment, order the following and record the accession number:					
			, ,		ts, you can use real patient orders. J	ust make
	sure y	ou reco	rd the applicab	le accession	number.	
		UACM	P: Accession	on		
		UMAC:	Accession	on	*positive specimen	
		UMAC:	Accession	on	*negative specimen	
		UDIP:	Accessio	on		
2.	Analy	ze the a	bove four samp	oles on the Iri	s.	
		Verify U	JACMP perform	ns microscop	pic.	
		Verify I	JMAC (positive	specimen) p	performs microscopic.	
		Verify l	JMAC (negative	e specimen)	does NOT perform microscopic.	
		Verify I	JDIP does NO	r perform mid	croscopic.	
		Save A	dvantus printo	uts for all fou	r specimens and attach to this form.	
3.	Verify	exampl	es of the follow	ing and reco	rd applicable accession number:	
		Patient	with glucose ≥	500 mg/dL:	Accession	
		Save A	dvantus printo	ut for specim	en.	
		Hint: C	Order a test pati	ient and use	positive control material.	

Iris (Alamance) Go Live Tasks

All of these tasks/items are in the Live (NC2) environment. Do not use TEST81 or TESTAR.

Please initial as these tasks/items are completed/verified.

Important Note: If ordering a test patient in NC2, please use TEST- to generate MRN.

1.	In Live environment, order the following and record the accession number: In lieu of manually ordering the below tests, you can use real patient orders. Just make sure you record the applicable accession number.
	UACMP: Accession
	□ UACMP: Accession *positive specimen
	□ UMAC: Accession ^negative specimen
	□ UDIP: Accession
2.	Analyze the above four samples on the Iris.
	 Verify UACMP performs microscopic.
	 Verify UMAC (positive specimen) performs microscopic.
	 Verify UMAC (negative specimen) does NOT perform microscopic.
	 Verify UDIP does NOT perform microscopic.
	 Save Iricell printouts for all four specimens and attach to this form.
	If printout does not automatically print, please request printed copy from Iricell.
3.	Verify BIOCH comment is automatically added in Sunquest for urines with colors other
	than yellow, straw or colorless:
	In lieu of manually ordering the below tests, you can use real patient orders. Just make
	sure you record the applicable accession number.
	□ UACMP: Accession
	□ UMAC: Accession
	□ UDIP: Accession
4.	Verify examples of the following and record applicable accession number:
	□ Patient with glucose ≥ 500 mg/dL: Accession
	□ Patient with total protein ≥ 300 mg/dL: Accession
	Hint: Order a test patient and use CB as test material. This control has greater
_	than values for both glucose and total protein.
5.	Verify USPRM in female < 16 years old does not autofile in Sunquest.
	□ Order UACMP on 14 year old female: Accession
	 Perform analysis and add USPRM to microscopic results.
	□ Release results to Sunquest.
	□ Report results in Sunquest.
	☐ Attach copy of Iricell printout to this form.
3.	Verify UCOL BLUE and RED do not autofile in Sunquest
	□ Order UDIP: Accession: (red)
	□ Order UDIP: Accession: (blue)

		Perform analysis and change colors to red or blue.		
		Release results to Sunquest.		
	 Report results in Sunquest. 			
	 Attach copy of Iricell printout to this form. 			
7.	Verify	y UNCX present does not autofile in Sunquest		
		Order UACMP: Accession:		
		Perform analysis and classify particle as UNCX.		
		Release results to Sunquest.		
		Report results in Sunquest.		
	П	Attach copy of Iricell printout to this form		

Once completed, please scan and email this checklist and supporting documentation to Jackie Hobbins.



TO:

Cone Health Hospital Providers

FROM:

Joshua B. Kish, MD, FCAP, FASCP

Chief of Pathology, Cone Health

John Patrick, MD, FCAP

cone Health Julia Patient, we 12/1/17 Medical Director, Clinical Pathology, Cone Health

DATE:

December 1, 2017

SUBJECT: Urinalysis Standardization, Effective December 5, 2017

The Cone Health hospital laboratories will standardize urinalysis reporting at all locations. Annie Penn, Moses Cone, Women's, and Wesley Long will implement new instrumentation, iRICELL® 1500/2000 Automated Urinalysis Workcells. This technology is already in use at Alamance Regional and provides urine biochemical testing with fully automated microscopy. When coupled with reflex microscopy protocols, the iRICELL® 1500/2000 will reduce urinalysis turnaround times.

In order to maximize benefits from new technology and standardize reporting across locations. the laboratory has updated reporting structures and Cone HealthLink orders.

Important Reporting Changes:

Change	Alamance Current	Greensboro/Reidsville Current	New Cone Health
Semiquantitative Result	Negative, 1+, 2+, 3+	Negative, Small,	Negative, Small,
Format		Moderate, Large	Moderate Large

Important Order Changes:

Order	Order Code	Description
Urinalysis, Macroscopic with Reflex Microscopic	LAB348	Microscopic performed only with positive protein, blood, nitrite, leukocytes, or glucose ≥ 500 mg/dL
Urinalysis, Dipstick Only	LAB9026	Urine biochemical testing only, no microscopic
Urinalysis, Complete	LAB9197	Urine microscopic always performed

Please note: For faster turnaround times, please use Urinalysis Macroscopic with Reflex Microscopic order when applicable.

For further information, please contact the following:

Dr. Joshua Kish: jbkish@auroradx.com or 336-832-8074 Dr. John Patrick: jdpatrick@auroradx.com or 336-832-8074