Status **Active** PolicyStat ID **16394957**

Origination	9/5/2024	Document Contact	Tanya Williams: Medical Technologist Lead
Last Approved	9/5/2024	Area	Laboratory-Urinalysis
Effective	9/5/2024	Applicability	Taylor + Trenton + Wayne
Last Revised	9/5/2024		
Next Review	9/5/2026		

Urinalysis Autoverification Policy

I. PURPOSE AND OBJECTIVE:

It is the department policy that all normal results and selected abnormal results from the urinalysis analyzers will be auto-verified in the laboratory's LIS.

The purpose of this document is to provide technical staff with policies and rules for autoverification of Urinalysis results as obtained from the Sysmex UN2000 Urinalysis Data Manager ~~and the~~or standalone Clinitek ~~analyzers~~analyzer.

II. ACRONYMS:

1. UDM=Urinalysis Data Manager
2. LIS=Laboratory Information System
3. XTL=Crystal
~~3~~4. YLC=Yeast Like Cell
~~4~~5. PCAST=Pathologic Cast
~~5~~6. RBC/YLC=Red Blood Cell/Yeast Like Cell
~~6~~7. BLD=Blood
~~7~~8. XCheck=Cross Check
~~8~~9. WBC=White Blood Cell
~~9~~10. LEU=Leukocytes
~~10~~11. NIT=Nitrite
~~11~~12. BACT=Bacteria

III. VALIDATION AND AUTOVERIFICATION

Validation of autoverification is performed annually or anytime the LIS database is altered. The procedure involves review of patient samples that have been previously tested and either passed or failed the stated criteria. There is a zero-tolerance system for errors in the LIS software application. Any detected failure of the software system to release or not to release sample results for autoverification is reported to the Information Technology team for review, correction and or modification of the LIS.

IV. PROCEDURE:

Sample results for each analyte within the autoverification range can be obtained by review of patient samples previously tested for routine Urinalysis. The reviewer has the opportunity to monitor recently completed patient test results, or order new dummy test patient requests in the LIS. The reviewer evaluates each criterion individually, in the same way that a new patient sample would be tested, resulted and reviewed. Validation requires that test results be processed through the UDM to the LIS interface or from the Clinitek Standalone analyzer to the LIS.

Autoverification Criteria

Clinitek Standalone Analyzer

When all of the following criteria are evaluated as "True", and no rule flags are sent from the Clinitek, then the LIS system will autoverify the urinalysis results.

Criteria Name	Range
Color	Autoverify if Yellow
Clarity	Autoverify if Clear
Glucose	Autoverify if Negative
Bilirubin	Autoverify if Negative
Ketones	Autoverify if Negative
Specific Gravity	Autoverify if 1.005-1.030
Blood	Autoverify if Negative
pH	Autoverify if 5.0-8.0
Protein	Autoverify if Negative
Urobilinogen	Autoverify if <2.0
Nitrite	Autoverify if Negative
Leukocyte Esterase	Autoverify if Negative

~~Sysmex UN2000 Urinalysis Analyzer~~**Sysmex UN2000 Urinalysis Analyzer**

When all of the following criteria are evaluated as "True", and no rule flags are sent from the UDM, then the LIS system will autoverify the urinalysis results.

Criteria Name	Range
Color	Autoverify if yellow or dark yellow
Clarity	Autoverify if clear, cloudy, turbid
Glucose	Autoverify if negative, 1+, 2+,3+, 4+
Bilirubin	Autoverify if negative, positive
Ketones	Autoverify if negative, 1+, 2+
Specific Gravity	Autoverify if 1.005-1.030
Blood	Autoverify if negative, 1+, 2+, 3+, 4+
pH	Autoverify if ≤ 9
Protein	Autoverify if negative, 1+, 2+,3+, 4+
Urobilinogen	Autoverify if 0.2, 0.4, 1.0, 2.0, 4.0, ≥8.0
Nitrite	Autoverify if negative, positive
Leukocyte Esterase	Autoverify if negative, 1+, 2+,3+, 4+
RBC	Autoverify if 0-2, 3-5, 6-10, 11-20, >20
WBC	Autoverify if 0-2, 3-5, 6-10, 11-20, 21-50, 51-100, >100
Epithelial Cells	Autoverify if 0-2, 3-5, 6-10, 11-20, >20
Casts	Autoverify if 0-2, 3-5
Bacteria	Autoverify if negative, occasional, 1+, 2+, 3+, 4+, ++++

~~The following criteria should hold in the LIS based on rules built in the UDM.~~**The following criteria should hold in the LIS based on rules built in the UDM.**

Rule #	Rule Name	Description
20	UFCastRev	Cast increased [>= 6/LPF], increased casts present, review cast type
21	UFXTAL	XTAL flag, Follow SOP for the presence of crystals
22	YLCFlag	YLC flag, Follow SOP for the presence of Yeast
23	PCASTFlag	PCAST flag, Follow SOP for the presence of non-hyaline casts
25	SPERMFlagOptional	SPERM flag, Follow SOP for the presence of sperm
26	DEBRIS	[Debris High], Follow SOP, confirm results
27	RBCYLC	[RBC/YLC Abn Cls], possible overlap of RBC and YLC. Follow SOP, confirm results
28	URINECOND	[ABN Conductivity], Possibility of red cell deformation or insufficient volume of sample
30	BLDXCheck	BLD is [>=Small/1+]and UF RBC [<=5 cells/HPF].Follow SOP, confirm results
31	RBCXCheckDefault	UF RBC [>=6 cells/HPF] and BLD [Neg], Follow SOP, confirm results
34	WBCXCheckDefault	UF WBC [>= 11 cells/HPF] and LEU [NEG], Follow SOP, confirm results

Rule #	Rule Name	Description
36	NITXCheck	If NIT [POS] and UF BACT [NEG], Follow SOP, confirm results
91	UFRBCDisp	UFRBC >99,999/µL, block output of ++++ to LIS
92	UFWBCDisp	UFWBC >99,999/µL, block output of ++++ to LIS
93	UFECDisp	UFEC >99,999/µL, block output of ++++ to LIS
94	UFCASTDisp	UFCAST >99,999/µL, block output of ++++ to LIS

Attachments

Urinalysis Autoverification Worksheet.pdf

Approval Signatures

Step Description	Approver	Date
Medical Directors	Muhammad Arshad: Chief, Pathology	9/5/2024
Policy and Forms Steering Committee Approval (if needed)	Tanya Williams: Medical Technologist Lead	9/3/2024
	Kristie Chennault: Supv, Lab Processing	9/3/2024
	Helen Anonick: Supv, Lab Processing	9/3/2024
	Katherine Persinger: Mgr, Laboratory	8/27/2024
	Marie Borg: Supv, Lab Processing	8/27/2024
	Ashley Beesley: Mgr, Laboratory	8/26/2024
	Kristen DiCicco: Mgr, Laboratory	8/22/2024
	Christopher Ferguson: Dir, Lab Services	8/21/2024
	Tanya Williams: Medical Technologist Lead	8/21/2024

Applicability

Taylor, Trenton, Wayne