465 Henry Mall • Madison, WI 53706 • (800) 462-5261 • FAX (608) 265-1111



Quality Assurance Urinalysis/Microscopy Programs Event 2012-2 Notes

Samples sent: August 6 - 7, 2012

This packet contains:

- ✓ Cumulative Summary Report: summarizes your performance over the last three events.
- Evaluation Report: detailed report of sample results for analytes reported by your laboratory for this event.
- ✓ Statistics Summary Report: scored peer group data for each reported analyte.
- ✓ Evaluation and Cumulative Summary Report keys can be found at the WSLH PT website: <u>https://www.slh.wisc.edu/dotAsset/27131.pdf</u>

Questions or comments should be directed to Barb Burmeister at 800-462-5261, x46 or Barbara.Burmeister@slh.wisc.edu

Scoring Notes

Performance Data: UR Event 2012-2:

- Number of participants who returned results = 1341 of 1368
- Analyte responses scored = 14725
- Number of analyte failures = 910 failures from 544 labs
- Overall analyte passing rate (scores $\geq 80\%$) = 93.8%

Not Scored/Creatinine: This analyte was not scored because <10 participants reported results. A supplemental statistics document has been included in the mailed reports for the affected participants to help with self-evaluation.

Nonconsensus/Reducing Substances: Sample UR12-2-1 for reducing substances did not reach $\ge 80\%$ consensus which is needed to score this analyte. Pre-event QA testing resulted in a Glucose level of 807 mg/dL (Beckman Coulter DxC 600). Two distinct reagent strip responses were noted for glucose. Nearly 75% of the respondents reported 150-250 and 17% reported \ge 1000. This may be due to the intense color of this sample, differences in methodology or failure to warm specimens to room temperature prior to testing.

The discrepancy in glucose results may have lead to the use of the 5 drop Clinitest method instead of the two drop method. Using the 5 drop method with a high glucose level may create a "pass-through" phenomenon where the reaction goes through all five color blocks but then turns a color most closely associated to negative or 1/4% color blocks due to a caramelization of the sugars present in the sample. If interpreted incorrectly, this will lead to false negative or falsely low results. Participants should take special care to observe the entire reaction as this caramelization affect occurs just after the reaction turns a bright orange resembling the 2% or more color block. Participants should also be able to observe the reaction proceeding through all five color blocks during this phenomenon.

Sample ID	Analyte	Responses	#	%
UR12-2-1	Reducing Substances	Negative	53	31%
		Trace (1/4%)	61	35%
		1/2 %	26	15%
		3/4%	18	10%
		1%	9	5%
		2%	7	4%

Not scored (N) flag: WSLH PT may choose to utilize this option in the following cases:

- ✓ If there are not enough participants using a specific instrument and/or method to create a statistically significant peer scoring group (n <5) and results from that instrument/method could not be combined with other related instruments/methods to constitute a valid peer scoring group.</p>
- ✓ If sample matrix or instrument/method incompatibility issues exist and results could not be scored by the "All Methods" scoring group.

In both cases, results are given an automatic 100% but the score may not be indicative of instrument/method performance. This action requires the participant to perform a written self-evaluation of the affected analytes/samples as per CLIA regulations. Participants should submit a **Data Request Form** for peer-group specific raw data, (available on-line at: <u>http://www.slh.wisc.edu/pt/forms/</u>).

Referee Scoring (urine sediment & wet prep): Scoring for urine sediment and wet prep is based upon consensus among referee laboratories. If the referee laboratories reach 80% or greater consensus on a sample, WSLH PT is required to score that sample according to the results obtained by the referee laboratories. Referee laboratories are selected from currently enrolled participants who achieved successful performance for the past three events and represent a mixture of both moderately complex and highly complex classifications.

Disagreement with referee accepted responses can be documented on the participant's review of proficiency testing results, but scores CANNOT be changed by the proficiency provider.

Qualitative/Semi-quantitative scoring policies: Qualitative responses (positive/negative) are scored based on 80% or greater consensus for each method or peer group. Semi-quantitative responses are scored based on the **mode** (most frequent response) for each method or peer group. The mode and, usually, one response above and one response below the mode are considered acceptable. Additional responses (no more than four) may be selected until 80% or greater consensus is reached. If the mode reaches a consensus of 90% or greater, additional responses may not be accepted. Negative responses will not be added to positive responses to achieve 80% consensus. Methods that do not achieve 80% or greater consensus will not be scored and will automatically be given a 100% score for the challenge. A qualitative statistics summary, included in your packet, may be used to review the results of your particular method and see where other methods rank in comparison to your method.

Invalid test results: Multiple response bubbles filled in for a single sample/analyte were classified as <u>invalid</u> and automatically given a <u>0% score</u>. To avoid this type of error, please review your result form carefully before submission to WSLH PT.

Confirmatory Tests: Confirmatory tests should be performed in accordance with laboratory protocol and accreditation agency requirements. If in following this protocol and fulfilling your requirements, you have NOT reported confirmatory results for this event and you have previously reported these results, you will see "NOT REPORTED" on your Cumulative Summary Report for any unreported confirmatory tests for this event. Be sure to properly document and follow your in-house procedures, and keep copies of all documentation with your proficiency testing records.

Reporting of multiple sets of results: Participants wishing to submit more than one set of results must be enrolled in additional result reporting programs. Participants that submitted multiple sets of results for Event 2012-2 but were not enrolled for multiple sets, did not have these additional sets evaluated. To have these sets evaluated for Event 2012-2 and receive a corrected report, please contact WSLH PT to update your proficiency testing order and associated charges.

Next Event Ships: January 28, 2013 Re-enrollment letters will be arriving soon. Participants MUST re-enroll to receive samples in 2013!

URINE SEDIMENT AND WET PREP SAMPLE INFORMATION

SU12-2-1/PM12-2-1 Urine Sediment

This is an example of a hyaline cast exhibiting fine granulation. Hyaline casts appear colorless with rounded ends and often have various shapes and sizes. Increased numbers of hyaline casts are often seen following extreme physiologic conditions (e.g., strenuous exercise, fever, or emotional stress).

A list of referee and participant responses appears in Table 1.

The correct responses for the challenge are:

- Hyaline Cast
- Granular Cast
- Would refer abnormal

Table 1. SU12-2-1/PM12-2-1 Distribution of Responses

Response	Referee		Participant	
	#	%	#	%
Hyaline Cast	26	58	441	60
Granular Cast	15	33	258	35
Would refer - abnormal	3	7	7	<1
Waxy Cast	-	-	10	<2
Other	1	2	18	3

SU12-2-2/PM12-2-2 Urine Sediment

This is an example of a calcium oxalate crystal. The arrow in the photo is pointing to a monohydrate form of calcium oxalate, which has a biconcave disk shape, appearing as a dumbbell when viewed from the side. There is also a dihydrate form of calcium oxalate in the photo, which appears as an envelope shape. Sulfonamides, in contrast, appear as bundles of needles (or sheaves of wheat) and have irregular radial striations.

A list of referee and participant responses appears in Table 2.

The correct responses for the challenge are:

- Calcium Oxalate Crystal
- Would refer abnormal

Table 2. SU12-2-2/PM12-2-2 Distribution of Responses

Response	Referee		Participant	
	#	%	#	%
Calcium Oxalate Crystal	34	76	522	71
Would refer - abnormal	4	9	22	3
Sulfonamides	4	9	120	16
Uric Acid Crystal	2	4	20	3
Leucine Crystal	1	2	2	<1
Calcium Carbonate Crystal	-	-	12	2
Artifact	-	-	13	2
Other	-	-	26	4

PM12-2-1 Wet Prep

The arrowed structure in this image is a clue cell. To be reported as a clue cell, most (but not all) of the cell surface should be covered with bacteria and the bacteria should extend past the cytoplasmic margins. For participants who report the presence/absence of clue cells/yeast/*Trichomonas* in wet prep specimens, the response "Clue cells/yeast/*Trichomonas* present" is an acceptable answer. Please remember, if you are using these responses, it must be in accordance with your laboratory's protocol for reporting patient results.

A list of referee and participant responses can be found in Table 3.

The correct responses for the challenge are:

- Clue cell
- Clue cells/ yeast/ Trichomonas present
- No Trichomonas present
- No yeast/fungal elements present

Table 3. PM12-2-1 Distribution of Responses

Response	Referee		Participant	
	#	%	#	%
Clue cell	21	81	587	80
Clue cells/yeast/Trichomonas present	1	4	35	5
No Trichomonas present	-	-	9	1
No yeast/fungal elements present	-	-	1	<1
Squamous epithelial cell	3	12	79	11
Other	1	4	20	3

PM12-2-2 Wet Prep

The arrowed structure in this image is pseudohyphae. This challenge shows pseudohyphae and budding yeast. This is indicative of a vaginal yeast infection. For participants who report the presence/absence of clue cells/yeast/*Trichomonas* in wet prep specimens, the response "Clue cells/yeast/*Trichomonas* present" is an acceptable answer. Please remember, if you are using these responses, it must be in accordance with your laboratory's protocol for reporting patient results.

A list of referee and participant responses can be found in Table 4.

The correct responses for the challenge are:

- Yeast/hyphae
- Clue cells/ yeast/ Trichomonas present
- No Trichomonas present

Table 4. PM12-2-2 Distribution of Responses

Response	Referee		Participant	
	#	%	#	%
Yeast/hyphae	26	100	706	97
Clue cells/yeast/Trichomonas present	-	-	5	<1
No Trichomonas present	-	-	4	<1
Other	-	-	14	2

Please review the reports carefully before filing this packet with the rest of your PT records. Documentation of all decisions and actions concerning incorrect responses should be maintained with your event reports to satisfy regulatory requirements. After trouble-shooting or corrective actions are completed and documented, all reports should be reviewed, signed/initialed by the appropriate personnel, and filed with your proficiency testing records to document your participation.