

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2107019	(X3) Date Survey Completed 04/19/2022
Name of Provider or Supplier Ourmed Llc	Street Address, City, State 9188 Eastchase Parkway, Montgomery, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing records and an interview with Testing Personnel #1, the Laboratory failed to verify the accuracy of Urine Sediment and Vaginal Wet Preparation - KOH that was not evaluated by API. This was noted on two out of six 2020 - 2021 Hematology Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2020 Hematology 2nd Event - Urine Sediment sample 6 was not graded due to no consensus. b) 2021 Hematology 3rd Event - Vaginal Wet Preparation - KOH was not graded and stated to see data summary. 2. During an interview on 04/19/2022 at 12:40 PM, Testing Personnel #1 confirmed the above events were not graded by API and a self evaluation of the results were not performed.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:
 Based on reviews of proficiency testing (PT), quality assurance (QA) records, and an interview with Testing Personnel #1, the laboratory failed to ensure the corrective actions taken effectively remediated problems identified in the general laboratory systems. This was noted from March 2020 to April 2022. The findings include: 1. A review of the 2020 - 2022 American Proficiency Institute (API) Proficiency Testing records revealed the laboratory failed three out of six of Urine Sediment PT and Vaginal Wet Preparation PT challenges as follows: a) 2020 - Hematology 1st: Urine Sediment score of 50% and Vaginal Wet Preparation score of 0% b) 2020 - Hematology 2nd: Urine Sediment score of 50% c) 2020 - Hematology 3rd: Vaginal Wet Preparation score of 0% d) 2021 - Hematology 1st: Vaginal Wet Preparation score of 0% e) 2021 Hematology 2nd: Urine Sediment score of 50%, Vaginal Wet Preparation score of 0%, and Vaginal Wet Preparations (KOH) score of 0%. 2. The laboratory documented remedial training for the individual who performed the PT events as corrective action for each failure. 3. A review of March 2020 - March 2022 monthly Quality Assurance Checklist included Proficiency Testing. The reviewer always answered "Y"(Yes) to "If corrective action was taken, has the problem been corrected over time?" 4. During an interview on 04/19/2022 at 12:40 PM, Testing Personnel #1 confirmed the corrective action for the PT failures listed above were the same and the improvement of performance has not occurred.

D5433

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
 Based on a review of Brightfield Microscopy Procedure, lack of maintenance logs, and an interview with Testing Personnel #1, the laboratory failed to implement and document their maintenance procedure for the Microscope used for Urine Sediments, Vaginal Wet Preparations, and Potassium Hydroxide (KOH). This was noted from previous survey (01/22/2020) to current survey (04/19/2022). The findings include: 1. A review of Brightfield Microscopy Procedure revealed a daily, monthly, and annual maintenance should be performed and documented for the Microscope. 2. The laboratory did not document any maintenance for the Microscope. 3. During an interview on 04/19/2022 at 1:55 PM, the Testing Personnel #1 confirmed no maintenance was documented for the Microscope.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
 (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory's Procedure Manual and an interview with Testing Personnel #1, the laboratory failed to have a control procedure in place for Urine Sediments, Vaginal Wet Preparations, and Potassium Hydroxide (KOH). This was noted from previous survey (01/22/2020) to current survey (04/19/2022). The findings include: 1. A review of the Laboratory's Procedure Manual revealed no sections which covered the quality control for Urine Sediments, Vaginal Wet Preparations, and Potassium Hydroxide (KOH). 2. During an interview on 04/19/2022 at 1:15 PM, Testing Personnel #1 confirmed the staff used no photomicrographs, charts, or liquid controls for Urine Sediment, Vaginal Wet Preparations, and Potassium Hydroxide (KOH).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with Testing Personnel #1, the Technical Consultant (also, the Laboratory Director) failed to assess all six competency assessment criteria required for moderate complexity testing. This was noted from previous survey (01/22/2020) to current survey (04/19/2022) for Complete Blood Count (CBC), Urine Sediments, Vaginal Wet Preparations, and Potassium Hydroxide (KOH) testing. The findings include: 1. A review of personnel records revealed the Competency Evaluation Checklist consisted of the procedure name, check-off date, employee initials, and proctor initials. This checklist did not include the six competency assessment criteria required for moderate complexity testing as follow: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f) Assessment of problem solving skills. 2. During an interview on 04/19/2022 at 3:30 PM, Testing Personnel #1 confirmed Competency Assessment being performed on employees does not include the six required criteria.