| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 24D0398704 | 08/04/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Quest Diagnostics-Minnesota Community Care Rrl | 895 East 7th Street, Saint Paul, MN | |

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 |
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| **D0000** | The Quest Diagnostics - Minnesota Community care RRL laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the (initial certification, recertification, validation) survey performed on August 4, 2026. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1291 Test report . |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and an interview with laboratory personnel, the laboratory failed to complete and document proficiency testing (PT) corrective action activities for one of six Urine Sediment Microscopy challenges completed in 2025. Findings are as follows: 1. The laboratory performed Urine Sediment Microscopy testing under the Urinalysis subspecialty as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 08/04/26. 2. The laboratory performed PT using the College of American Pathologists (CAP) proficiency testing provider. 3. Investigation and corrective action for unacceptable PT results was required as established in the Policy for Review and Evaluation of Proficiency Testing Results found in Smartsolve, the laboratory's procedure management software. 4. The CAP Clinical Microscopy event 2025 CM-B report indicated the Urine Sediment Microscopy sample USP-06 result was unacceptable. See below CAP 2025 CM-B event Sample: USP-06 CAP expected result: Erythrocyte Laboratory result: Fat droplet 5. The laboratory's corrective action for the unacceptable result indicated training and additional assessment would occur for the testing personnel involved. Documentation of the training and additional assessment was not found during review of laboratory record QDMOQ304-2025-1200 located in the laboratory's quality |

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| | improvement software MediaLab. The laboratory was unable to provide the missing documentation upon request. 6. In an interview at 11:50 a.m. on 08/04/26, TC1 confirmed the above findings. . |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure four of four Vaginal Wet Preparation (VWP) analyte reference intervals were included on a patient test report in 2025. Findings are as follows: 1. The laboratory performed a four analyte VWP microscopic examination under the Bacteriology, Mycology, and Parasitology subspecialties as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 08/04 /26. 2. An Olympus BX45 microscope and potassium hydroxide solution were observed as present and available for use during the tour. These items were used to perform the VWP examination. 3. Four of four VWP analyte reference intervals found in the Wet Mount (Vaginal) for Clue Cells, Yeast, and Trichomoniasis Vaginalis procedure, located in the laboratory's document management software Smartsolve, were not listed on the patient test report from 03/03/25 reviewed on date of survey. Patient MRN ....130, tested on 03/03/25 Analytes reported Trichomoniasis vaginalis Yeast Clue cells Epithelial cells 4. The laboratory performed approximately 340 VWP tests annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 5. In an interview at 2:30 p.m. on 08/04/26, TC1 confirmed the above finding. . |