

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1074961	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Urgent Care Northwest	Street Address, City, State 2708 Highway 78 East, Jasper, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to evaluate the results for a PT score less than 100%. This is noted for one of seven events from 2020 to 2022. The findings include: 1. A review of the MLE PT records revealed the following score: 2021 MLE - M1 event, the laboratory scored 50% for Urine Sediment Exam with no corrective action documented. The laboratory reported Red Blood Cells (RBC) for US - 1 and the acceptable result was Phosphate Crystals. 2. During an interview on 05/24/2022 at 4:50 PM, Testing Personnel #1 confirmed corrective action was not documented for Urine Sediment MLE - M1 event.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Qualigen FastPak Quality Control (QC) records, review of the Individualized Quality Control Plan (IQCP), and an interview with Testing Personnel #1, the laboratory failed to follow the IQCP for Thyroid Stimulating Hormone (TSH), Free Throxine (FT4), and Testosterone (Testo). This was noted in two out of twenty-eight months reviewed by the surveyor. The findings include: 1. A review of the Qualigen FastPak QC records revealed the following: a) FT4, TSH, and Testo weekly QC was not performed on 09/17/2020 (previous QC was performed on 09/10/2020 and the next QC was performed on 09/24/2020). i) FT4 had five patients performed from 09/18/2020 to 09/21/2020 ii) TSH had seven patients performed from 09/18/2020 to 09/22/2020 iii) Testo had two patients performed from 09/20/2020 to 09/22/2020 b) TSH weekly QC not performed on 12/23/2021 (previous QC was performed on 12/16/2021 and the next QC was performed on 12/30/2021); one patient TSH was performed on 12/23/2021. 2. A review of the Qualigen IQCP revealed, "...Level 1 and Level 2 controls must be run every week on Thursday unless lab is closed. If closed, QC will be performed the next day...". 3. During an interview on 05/24/2022 at 4:00 PM, Testing Personnel #1 confirmed the above noted findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the Qualigen FastPak Quality Control (QC) records, review of the Individualized Quality Control Plan (IQCP), and an interview with Testing Personnel #1, the laboratory failed to follow the IQCP for Free Throxine (FT4) to ensure at least two levels of QC were run and acceptable prior to patient testing. This was noted in two out of twenty-eight months reviewed by the surveyor. The findings include: 1. A review of the Qualigen FastPak QC records revealed the following: a) FT4 weekly QC was run on 04/01/2021, but was unacceptable and not rerun until 04/08/2021; three patients FT4's were performed from 04/05/2021 to 04/07/2021. b) FT4 weekly QC was run on 11/26/2021, but was unacceptable and not rerun until 12/02/2021; three patient FT4's were performed from 11/26/2021 to 11/30/2021. 2. A review of the Qualigen IQCP revealed "...Ensure that control results are within the expected values for each control lot...". 3. During an interview on 05/24/2022 at 4:00 PM, Testing Personnel #1 confirmed the above noted findings.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on a review of the MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to

assess the effectiveness of corrective actions taken to prevent recurring failures in Microscopy (Urine Sediment Exam) surveys. The surveyor noted the laboratory failed four of seven surveys from 2020 - 2022. The findings include: 1. A review of the MLE PT records revealed the following failures in Urine Sediment Microscopy surveys: a) 2020 MLE - M3: Urine Sediment 50% (US- 5 Laboratory resulted: White Blood Cells (WBC); Acceptable result: Transitional Epithelial Cell) b) 2021 MLE - M1: Urine Sediment 50% (US - 1 Laboratory resulted: Red Blood Cell (RBC); Acceptable result: Phosphate Crystal) c) 2021 MLE - M3: Urine Sediment 50% (US - 6 Laboratory resulted: Red Blood Cell (RBC); Acceptable result: Fat droplets on globules) d) 2022 MLE - M1 Urine Sediment 0% (US-1 Laboratory resulted: Transitional Epithelial Cell; Acceptable result: Renal Tubular) (US-2 Laboratory resulted: Fat Droplets on Globules; Acceptable result: Bacteria) 2. A review of corrective actions for the above failures revealed the following: a) 2020 MLE - M3: "Clicked wrong result." b) 2021 MLE - M1: no corrective action was documented by the laboratory. c) 2021 MLE - M3: "Discussed results with Laboratory Director." d) 2022 MLE - M1: "Went over results with Medical Doctor before submitting." There was no documentation of additional corrective actions to prevent recurrence. 3. During an interview on 05/24/2022 at 4:50 PM, Testing Personnel #1 confirmed the the above noted findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to provide documentation of annual competency evaluations for all moderate complexity test systems utilized in the laboratory. This was noted for the lack of evaluations for Vaginal Wet Preparation documentation on three of five Testing Personnel listed on the CMS-209 Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the following: a) Testing Personnel #1's annual competency evaluations were performed on 09/17/2020 and 09/19/2021, however the competencies did not include Microscopic procedures for Vaginal Wet Preparation. b) Testing Personnel #2's semi-annual competency evaluation was performed on 02/10/2022, however the competency did not include Microscopic procedures for Vaginal Wet Preparation. c) Testing Personnel #5's semi-annual competency evaluation was performed on 02/28/2022, however the competency did not include Microscopic procedures for Vaginal Wet Preparation. 2. During an interview on 05/24/2022 at 2:39 PM, Testing Personnel #1 confirmed the competency evaluation forms did not include Microscopic procedures for Vaginal Wet Preparation.