

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1077115	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Concentra - Morrow	Street Address, City, State 1500 Mt Zion Road, Morrow, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 15, 2020. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of the laboratory standard operation procedure manual (SOP), and staff interview, the laboratory failed to follow procedure for labeling waived test specimens by the laboratory. Findings include: 1. Observation during the laboratory tour on 12/15/2020 at approximately 10:10 a.m. revealed a urine specimen labeled with only the patient name. 2. Review of the SOP Urinalysis procedure dated 7/18/18 reveals the specimen is to be labeled with the patients name, date of birth, date & time of collection, and the collection staff's initials. 3. An interview with the technical consultant in the breakroom at approximately 11:10 a.m. on 12/15/2020 confirmed the lack of required labeling components on the observed sample.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the laboratory technical consultant, the laboratory testing personnel (TP) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of PT records revealed TP did not sign the 2019 event #3 attestation statement. 2. Interview with the laboratory technical consultant on 12/15/20 in the breakroom at approximately 11:15 am, confirmed the attestation was not signed by the TP.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of staff documents and staff interview, the laboratory failed to perform annual competency on the technical consultant (TC). Findings include: 1. Review of the staff educational and competency documents reveals the lab failed to ensure the TC was competent in her duties with annual competency evaluations. 2. Interview with the lab technical consultant on 12/15/2020 in the breakroom at approximately 11:00 am, confirmed the lack of the aforementioned documents.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on lab report review and staff interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings include: 1. Review of patient report #117478520 revealed the test report not include units of measurement or reference range for the complete blood count analytes. 2. Interview with the lab technical consultant and the office manager on 12/15/2020 in the breakroom at approximately 11:30 am, confirmed the absence of the units of measurement and reference range.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of staff documents and staff interview, the laboratory director (LD) failed to perform annual competency on the technical consultant (TC). Findings include: 1. Review of the staff educational and competency documents reveals the LD failed to ensure the TC was competent in her duties with annual competency evaluations. 2. Interview with the lab technical consultant on 12/15/2020 in the breakroom at approximately 11:00 am, confirmed the lack of the aforementioned documents.

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 review of testing personnel(TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of testing personnel(TP) documents reveals the lack of 2019 and 2020 competency records on staff #5 (CMS 209). 2. Interview with the lab technical consultant on 12/15/2020 in the breakroom at approximately 11:00 am, confirmed the lack of the aforementioned documents.