

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1077115	(X3) Date Survey Completed 11/29/2018
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 November 29, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
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 competency evaluation policy & procedure review and staff interview, the lab did not include all six (6) minimal requirements for the assessment of personnel competency. Findings include: 1. Review of the employee competency evaluation procedures revealed the lab did not monitor the recording and reporting of test results. 2. Review of the employee competency evaluation procedures revealed the lab did not monitor the assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. 3. Interview with the technical consultant (CMS 209) on 11/29/18 in the practice manager's office at 10:54 AM confirmed the the missing required components of the competency evaluations.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),</p>

which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of temperature records and staff interview, the lab failed to document corrective actions when temperatures exceeded acceptable limits. Findings include: 1. Reviewed temperature records of April 2018 through May 2018 revealed the freezer was out of use until May 23, 2018. No corrective actions documented. 2. Interview with the technical consultant (CMS 209 form) on 11/29/17 at approximately 10:30 AM in the practice manager's office, confirmed the corrective actions were not documented.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) documents and an interview with the lab director, the technical consultant (TC) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of employee competency documents revealed the TC did not perform a 6 month evaluation on 4 of 5 newly hired testing personnel. 2. Interview with the technical consultant (CMS 209) on 11/29/18 in the practice manager's office at 10:53 AM confirmed the missing 6 month evaluations on 4 of the 5 newly hired testing personnel.