

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2132071	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier Metrohealth Andrology Lab	Street Address, City, State 12301 Snow Road, 4th Floor, Parma, OH	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Testing Personnel (TP), the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing results. All 120 patients tested at this lab in the year 2018 have the potential to be affected. Findings Include: 1. Review of the laboratory's manual, on 4/9/19, failed to find any proficiency testing policies and procedures. 2. An interview with the TP, on 4/9/19 at 12:17 pm, confirmed that the lab failed to establish a protocol for each step in the handling, preparation, processing, examination and reporting of proficiency testing results.</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>

This STANDARD is not met as evidenced by:
 Based on record review, and an interview with the Testing Personnel (TP), the laboratory failed to establish and follow a written policy and procedure to assess competency of the Clinical Consultant (CC), Technical Supervisor (TS) and General Supervisor (GS), as specified in the personnel requirements in subpart M. All 120 patients tested at this laboratory in the year 2018 have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 1/15/19, found 1 person serving as both CC and TS, and 1 person serving as GS. 2. Review of the laboratory's "Annual Review Competency Checklist" policy and procedure failed to find a policy and procedure for assessing the competency of the CC, TS and GS based on the regulatory responsibility of those roles. 4. An interview with the TP, on 4/9/19 at 12:07 pm am, confirmed that the lab did not have policy or procedure for assessing the competency of CC, TS and GS based on the regulatory responsibility of those roles.

D5435

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(b)(2)

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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
 Based on direct observation, record review and an interview with the Testing Personnel (TP), the lab failed to establish and follow maintenance and function check protocols on each piece of equipment it uses, including those that are peripherally involved in patient testing. All 120 patients tested at this lab in the year 2018 have the potential to be affected. Findings include: 1. A tour of the Metrohealth Andrology lab found equipment used in the testing of patient specimens, including: microscope, centrifuge, pipettes, timers, incubator, dry bath and thermometers. 2. Review of the laboratory's policies and procedures failed to find an established protocol for the aforementioned equipment maintenance function checks. 3. An interview with the TP, on 4/9/19 at 11:55 am, confirmed that the lab failed to establish and follow protocol for equipment maintenance and function checks for each piece of equipment it uses.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon a record review and an interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to specify the duties and responsibilities of 1 out of 1 Clinical Consultant (CC), and 1 out of 1 Technical Supervisor (TS) listed on the CMS-209. Findings include: 1. Review of the CMS-209 form found 1 individual listed as performing duties of a CC, and 1 individual listed as performing the duties of the TS. 2. Review of policies and procedures failed to find evidence that the duties and responsibilities of the CC and TS were specified in writing by the laboratory director. 3. An interview with the TP, on 4/9/19 at 12:07 pm, confirmed that the LD failed to specify the duties and responsibilities of the CC and TS in writing.