

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2006341	(X3) Date Survey Completed 06/23/2021
Name of Provider or Supplier Owensboro Health Medical Group Ob & Gyn	Street Address, City, State 1301 Pleasant Valley Road Suite 300, Owensboro, KY	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on 06/23/2021, the laboratory failed to perform sufficient quality assessment from 07/25/2019 through 06/22/2021. Findings include: 1. Record review revealed no policy in place for quality assessment as outlined by the laboratory director. 2. An interview of staff on 06/23/2021 at 10:25 AM revealed that from 07/25/2019 through 06/22/2021, there was no system to document quality assessment of pre-analytical, analytical, or post-analytical metrics.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on staff interview and procedure review on 06/23/2021, the laboratory failed to ensure that the clinic had policies for Quality Assurance, Expired Reagents and Competency Assessment from 07/25/2019 through 06/22/2021. The findings include: 1. Policy review conducted on 06/23/2021 revealed the laboratory did not have a procedure to detail how Competency assessment would be performed. 2. Policy review conducted on 06/23/2021 revealed the laboratory did not have a procedure to detail how Quality Assurance was performed and documented. 3. Policy review conducted on 06/23/2021 revealed the laboratory did not have a procedure to detail how the facility would check the laboratory for expired reagents. 4. An interview with the laboratory staff on 06/23/2021 at 11:37AM confirmed that the laboratory did not have a system to perform and document Quality Assurance, check the laboratory for expired reagents and document Competency Assessment.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and staff interview on 06/23/2021, the laboratory failed to ensure potassium hydroxide reagents in use had not exceeded the manufacturer's expiration date. Findings include: 1. Observation on 06/23/2021 at 12:36 PM revealed that twenty-three (23) out of twenty- three (23) potassium hydroxide vials were expired. 2. Procedure review on 06/23/2021 revealed the laboratory did not have a procedure for expired reagents. 3. Staff interview at 12:36 PM on 06/23/2021 revealed the laboratory failed to have a system in place to ensure reagents were discarded before the manufacturer's expiration date.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on staff interview and record review on 06/23/2021, the Technical Consultant failed to perform and document annual competency using the six (6) mandated

competency assessment requirements for testing personnel. Competency assessment was not performed using six (6) methods of assessment for four (4) out of fourteen (14) employees from 07/25/2019 through 06/22/2021. Findings include: 1. Record review on 06/23/2021 revealed there was no documented competency assessments between 07/25/2019 and 06/22/2021 for four (4) employee that included the following: competency assessments failed to include direct observation of routine patient test performance, direct observation of performance of instrument maintenance function checks and calibration, monitoring the recording and reporting of test results, review of worksheets, review of quality control records, review of proficiency test results, review of maintenance records, assessment of testing external proficiency testing samples and problem solving skills. An interview with the staff on 06/23/2021 at 10:00 AM revealed the facility failed to have a system in place between 07/25/2019 and 06/22/2021 to ensure competency was performed using all six (6) mandated competency assessment requirements.