

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0700499	(X3) Date Survey Completed 02/12/2025
Name of Provider or Supplier Metropartners Obstetrics & Gynecology, Pa	Street Address, City, State 2945 Hazelwood Ave N Suite 210, Maplewood, MN	
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	The Metropartners Obstetrics & Gynecology, PA laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the validation survey performed on February 12, 2025. The following standard-level deficiencies were cited: 493.801 Testing of proficiency testing samples 493.1105 Retention requirements 493.1251 Procedure manual 493.1413 Technical consultant responsibilities .
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 document review and interview with laboratory personnel, the testing personnel (TP) failed to attest to the integration of proficiency testing samples into the routine patient workload for one of three proficiency testing (PT) events reviewed from 2023. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. The laboratory performed PT using the American Association of Bioanalysts program in 2023. 3. All participating laboratory testing personnel (TP) were required to sign the attestation statements as established in the Proficiency Testing Guidelines policy found in the Procedure and Policy Manual. 4. Participating laboratory TP failed to sign one of three 2023 attestation statements found in the PT manual. See below. 2023 M2 Event - Chemistry 5. During an interview at 12:55 PM on 2/12/25, the Technical Consultant confirmed the above finding. .</p>

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least two years in 2023. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. The laboratory performed Microbiology PT using the American Association of Bioanalysts program in 2023. 3. The laboratory was required to retain all PT records as established in the Proficiency Testing procedure found in the Procedure and Policy Manual. 4. The following AAB PT documentation was not present in laboratory records on the date of survey. The laboratory was unable to provide these documents upon request. 2023 M3 Event results 2023 M3 Event attestation statement 5. In an interview at 12:55 PM on 2/12/2025, the TC confirmed the above finding. .

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the written procedure manual for the single Microbiology test system in use included all required elements in 2023 and 2024. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. A BD Affirm VPIII Microbial Identification Test system was observed as present and available for use during the tour. 3. The Quality Control For BD Affirm procedure found in the Procedure and Policy Manual was missing the

following required elements: -Requirements for patient preparation, specimen collection, labeling, storage, preservation, transportation, processing and criteria for specimen acceptability and rejection -Step-by-step performance of the procedure - Corrective action to take when the quality control results fail to meet criteria for acceptability -Normal values The laboratory was unable to provide a procedure with the missing elements upon request. 4. The laboratory performed 1,310 BD Affirm VPIII Microbial Identification tests on patient samples annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 5. In an interview at 1:43 PM on 2/12/25, the TC confirmed the above finding. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to ensure comprehensive initial training for seven of twelve new testing personnel (TP) was performed and documented in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the TC during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. The following instruments and equipment were observed as present and available for use during the tour: BD Affirm VPIII Microbial Identification System Olympus CH30 microscope A Candida, Gardnerella, and Trichomonas panel (MVP) was performed using the BD Affirm instrument and Vaginal Wet Preparations (VWP) were performed using the microscope. 3. Competency evaluation of all testing personnel was required at the time of initial training, after six months of work, one year after initial training, and annually thereafter as established in the Competency Training For Clinic Staff policy provided by the laboratory on the date of survey. 4. Documentation of VWP competency evaluation at the time of hire was not found for the following testing personnel: TP3, TP8, TP12. Documentation of BD Affirm MVP competency evaluation at the time of initial training was not found for the following testing personnel: TP16, TP21, TP24, and TP32. The laboratory was unable to provide the missing documentation upon request. 5. 1,320 moderate complexity Microbiology tests were performed annually as indicated on the Form CMS-116 provided by the laboratory on the date of survey. 6. In an interview at 12:20 PM on 2/12/2025, the TC confirmed the above finding. .

D6053

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

(b)(9) 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 observation, document review, and interview with laboratory personnel, the Technical Consultant (TC) failed to assess competency at least semi-annually during the first year of patient specimen testing for 4 of 12 testing personnel hired in

2023. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the TC during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. A BD Affirm VPIII Microbial Identification System was observed as present and available for use during the tour. A Candida, Gardnerella, and Trichomonas panel (MVP) was performed using the BD Affirm instrument. 3. Competency evaluation of all testing personnel was required after six months of work as established in the Competency Training For Clinic Staff policy provided by the laboratory on the date of survey. 4. Semi-annual MVP competency evaluations for the following testing personnel hired in 2023 were not found during review of laboratory records. The laboratory was unable to provide the missing competency evaluation upon request. Testing Personnel Hire Date TP16 1/10/2023 TP21 7/11/2023 TP24 8/14/2023 TP32 7/5/2023 5. 1,320 moderate complexity Microbiology tests were performed annually as indicated on the Form CMS-116 provided by the laboratory on the date of survey. 6. In an interview at 12:20 PM on 2/12/2025, the TC confirmed the above finding. .

D6054

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

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the Technical Consultant (TC) failed to assess competency at least annually for 1 of 20 testing personnel (TP) in 2023. In addition, the TC failed to assess competency at least annually for 15 of 29 TP in 2024. Findings are as follows: 1. The laboratory performed moderate complexity Microbiology testing as confirmed by the TC during a tour of the laboratory at 10:07 AM on 2/12/2025. 2. A BD Affirm VPIII Microbial Identification System was observed as present and available for use during the tour. A Candida, Gardnerella, and Trichomonas panel (MVP) was performed using the BD Affirm instrument. 3. Competency evaluation of all testing personnel was required annually as established in the Competency Training For Clinic Staff policy provided by the laboratory on the date of survey. 4. Annual MVP competency assessments were not found for the following testing personnel during review of 2023 and 2024 competency assessment documentation found in Employees CMS-MA-Lab manual. The laboratory was unable to provide the missing documentation upon request. See below. Missing Annual Competency Evaluations: 2023: TP31 2024: TP15, TP16, TP17, TP18, TP19, TP20, TP21, TP23, TP24, TP25, TP26, TP27, TP30, TP31, TP32 5. 1,320 moderate complexity Microbiology tests were performed annually as indicated on the Form CMS-116 provided by the laboratory on the date of survey. 6. In an interview at 12:20 PM on 2/12/2025, the TC confirmed the above finding. .