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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0211985 | (X3) Date Survey Completed 02/19/2025 |
| Name of Provider or Supplier Olney Pediatrics | Street Address, City, State 18111 Prince Philip Dr, Ste 311, Olney, MD | |
| 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 |
|---------------------------|--|
| 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 proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the individual testing or examining the samples and the LD signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures. Laboratory staff perform the specimen processing of throat swabs, inoculating the culture media and placing the culture plates in the incubator. The physicians on staff perform the testing, observing any bacterial growth and interpreting the culture plates. 2. A review of microbiology PT records from five events in 2023 and 2024 showed that in five of five events, the attestation statements were signed by the laboratory staff who performed the specimen processing, not by the physicians who performed the PT; and 3. In two of five PT events, the LD did not sign the attestation statements, attesting that PT specimens were run in the same manner as patient samples. 4. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that all of the attestations statements were not signed by the LD nor by the physicians performing the test.</p> |
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> |

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that microbiology PT results were evaluated and the review documented. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures. 2. A review of microbiology PT records from five events in 2023 and 2024 showed that in five of five events, the LD failed to sign the PT results report, documenting that the results had been reviewed and were acceptable. 3. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that there was no documentation that PT results had been evaluated and reviewed.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
I. Based on procedure manual, manufacturer's package insert, laboratory log, and patient record review and interview with the laboratory director (LD), the laboratory failed to provide written procedures for all aspects of performing bacteriology testing. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures using "BBL TSA II 5% SB" media and urine colony counts using "Uricult CLED/EMB" urine "Culture-Paddles." 2. CLIA regulations state that the laboratory must "Check each batch of media for sterility if sterility is required for testing; check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer." 3. Procedure manual review showed that the laboratory did not have a procedure, instructing the laboratory staff on how to perform quality checks on the media shipments received by the laboratory, or stating what it meant if the staff signed the "Strep Plates QC Log" or the "Uricult QC Log." 4. During an interview on 02/19/2025 at 11:00 AM, laboratory staff stated that throat and urine cultures are set up in another office ("Suite 310") and stored in a separate incubator before being transported to the main laboratory's incubator in "Suite 311." There was no written procedure available at the time of the survey for this process. 5. The "Patient Test Management" procedure stated to read throat cultures at "24 and 48 hours of growth"; however this conflicts with the package insert for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" which stated that culture plates must be incubated "at 35 to 37C for 18 to 24 hours" before being read or interpreted. 6. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory did not provide a written procedure manual for all tests, assays, and examinations performed by the laboratory. II. Based on procedure manual, manufacturer's package insert, and patient record review and interview with the laboratory director (LD), the laboratory did not follow written procedures for reporting the results of bacteriology testing. Findings: 1. The laboratory performs presumptive identification of group A streptococcus (strep) on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. The package

insert for the "BD BBL Taxo Discs for Differentiation of Group A Streptococci," under "Results" states, "It is recommended that any zone of inhibition, regardless of diameter, be reported as 'beta-hemolytic Streptococcus, presumptively group A by bacitracin'" and the section, "Limitations of the Procedure" states, "The Taxo A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." The package insert was included as part of the laboratory's procedure manual. 3. Random review of patient records showed that two of two patients' throat cultures were reported as "pos at 24 hours" (patient specimen collected 02/12/2025) and "pos at 24 hrs group A" (patient specimen collected 01/17 /2025), not "presumptive positive" as instructed in the "BD BBL Taxo Discs for Differentiation of Group A Streptococci" package insert. 4. During an interview on 02 /19/2025 at 1:45 PM, the LD confirmed that the laboratory reports "presumptive positive" strep test results as "positive" and did not follow written procedures for reporting bacteriology testing.

D5411

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on procedure manual, laboratory reagent package insert, and patient log record review and interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions for performing bacteriology testing. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. The procedure, "Patient Test Management" states that "if the rapid test is negative but the patient is symptomatic, a culture is plated, labelled, documented, and placed in incubator where it will be read at 24 and 48 hours of growth"; however 3. Review of the package insert for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" showed that culture plates must be incubated "at 35 to 37C for 18 to 24 hours" before being read or interpreted. 4. Review of "Olney Peds Throat and Urine Culture Logs" from 2024 and 2025 showed that the laboratory evaluated the culture plates at 24 and 48 hours after inoculation and did not follow the manufacturer's instructions for performing throat cultures using the Taxo A disc. 5. During an interview on 02/19/2025 at 1:45 PM the LD confirmed that the laboratory did not follow the manufacturer's instructions for performing throat cultures.

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on manufacturer package insert, procedure manual, and monthly temperature log record review, the laboratory failed to define the acceptable temperature range for room and incubator temperatures which were consistent with the manufacturer's instructions for performing bacteriology testing using purchased growth media. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures using "BBL TSA II 5% SB" media and urine colony counts using "Uricult CLED/EMB" urine "Culture-Paddles." 2. Review of the procedure, "Collection, Culture, and Interpretation of Throat Culture Screen for the Presumptive Identification of Group A Streptococci Companion Guide" showed that "BBL TSA II 5% SB" media used for throat cultures should be incubated at "35C-37C", however the laboratory's monthly temperature log stated that the acceptable incubator temperature range was "34 - 37 C." 3. A review of monthly temperature logs from May through August 2024 showed that the temperature of the incubator in "Suite 311" was out of the acceptable range recommended by the "Group A Streptococci Companion Guide" 14 out of 87 days recorded. 4. Review of the package insert for the "Uricult CLED/EMB" urine "Culture-Paddles" showed that the unopened paddles are to be stored at "7 ...25C", however the laboratory's monthly temperature log stated that the acceptable room temperature range was "20 to 32 C." 5. A review of monthly temperature logs from May through August 2024 showed that the room temperature in "Suite 311" was out of the acceptable range recommended by the "Uricult CLED/EMB" urine "Culture-Paddles" package insert, one out of 87 times recorded. 6. The package insert for the "Culture-Paddles" also states that the inoculated paddles should be incubated at "36C +/- 2C." Record review showed that the incubator in "Suite 311" was out of the manufacturer's acceptable range, two out of 87 days recorded. 7. Four out of four temperature logs for "Suite 311" were signed as having been reviewed by the LD. 8. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory failed to accurately define and monitor room and incubator temperatures to ensure accurate and reliable test system operation and test result reporting.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
 (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on record review and interview with the laboratory director (LD), the laboratory failed to ensure that the laboratory's Individualized Quality Control Plan (IQCP) for performing quality control (QC) on throat and urine culture media was complete, in order to reduce the frequency of QC testing required. Findings: 1. The laboratory performs presumptive identification of group A streptococcus (strep) on throat cultures as well as colony counts on urine cultures. 2. The laboratory records did not include documentation of two levels of QC each day of testing for throat and

urine cultures. 3. The laboratory is required to test two levels of QC materials each day of testing unless they have a written IQCP. Record review showed that the laboratory's IQCP for strep selective agar and urine culture agar included a Risk Assessment, but did not include the Quality Control Plan listing the number, type, frequency of testing & criteria for acceptable results of the QC or the Quality Assessment plan to monitor the effectiveness of the laboratory's IQCP. The IQCP was not approved (signed and dated by the LD). 4. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory failed to perform an IQCP in order to reduce the frequency with which microbiology QC was required.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on microbiology quality control (QC) record review and interview with the laboratory director (LD), the laboratory failed to perform and document QC on the lot number of "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" (Taxo A discs) currently in use in the laboratory. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. The laboratory performs QC on new lot numbers and shipments of Taxo A discs received, using purchased American Type Culture Collection (ATCC) organisms to confirm positive (using *Streptococcus pyogenes*, ATCC# 19615) and negative (using *Streptococcus agalactiae*, ATCC# 12386) reactivity. 3. Review of "Bacitracin Disc Quality Control" Logs from 2024 and 2025 showed that the laboratory filled out a "Bacitracin Disc Quality Control" log for the current lot number of Taxo A discs (lot#: 4023684, expiration date: 07/24/2025) on 11/06/2024, however the testing person failed to document the results for the positive and negative controls. The log was signed by the LD on 11/06/2024. 4. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory failed to document the results of QC for the current lot number of Taxo A discs prior to use for patient testing.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on procedure manual and microbiology record review, and interview with the laboratory director (LD), the laboratory failed to check each batch of selective streptococcus (strep) throat culture media and urine colony count media for sterility and the ability to support or inhibit growth of specific organisms, and to document the physical characteristics of the media when compromised, prior to use for patient testing. Findings: 1. Review of the "Strep Plates QC Log" worksheets for 2024 and 2025 showed that the laboratory documents the "Lot Number," "Expy Date," "Temp," "Qty Rec'd," and "Staff Initials/Date" and on the "Uricult QC Log" they record the "Lot Number," "Expy Date," "Qty Rec'd," and "Staff Initials/Date." 2. The logs did not document if the laboratory performed quality assurance checks on the condition of the culture media upon receipt. 3. Procedure manual review showed that the laboratory did not have a procedure, instructing the laboratory staff to perform quality checks on the media shipments received by the laboratory, or stating what it meant if the staff signed the QC logs. Cross-refer to D5401, part I 4. The laboratory had not completed an Individualized Quality Control Plan (IQCP) to eliminate the end user quality control requirements. Cross-refer to D5445 5. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory failed to document quality checks on throat and urine culture media prior to use for patient testing.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(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), 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 temperature log record review and interview with the laboratory director (LD), the laboratory failed to document corrective action when room and incubator temperatures were out of range. Findings: 1. The laboratory stores reagents for and performs bacteriology testing in two different offices, "Suite 310" and "Suite 311." The laboratory records the room temperature and incubator temperature in each office on a monthly log, labeled "310" or "311." The temperature log states that the acceptable room temperature range is "20 to 32 C" and that the acceptable incubator temperature range is "34 - 37 C." 2. A review of monthly temperature logs from May to August 2024 showed that room temperatures in Suite 310 were out of range 11 out of 87 days recorded, and that incubator temperatures in Suite 311 were out of range 12 out of 87 days recorded. 3. Temperature log review also showed that room and incubator temperatures were out of the manufacturer's acceptable range, which defines the criteria for accurate and reliable test system operation and test result reporting. Cross-refer to D5413 4. The temperature log has space at the bottom for "Any incident or action taken", however no corrective actions were documented for the out of range temperatures. 5. Eight out of eight temperature logs reviewed for "Suite 310" and "Suite 311" were signed as having been reviewed by the LD. 6. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory failed to

document corrective actions when room and incubator temperatures were out of acceptable range.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the quality assurance (QA) plan and interview with the laboratory director (LD), the LD failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified.

Findings: 1. A review of monthly QA logs from August 2023 to January 2025 showed that each of the tasks were checked off that they were acceptable. The LD signed off on 18 of 18 QA logs. 2. The LD's QA reviews failed to identify that neither the individual testing or examining proficiency testing (PT) samples nor the LD signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples. Cross-refer to D2009 3. The LD's QA reviews failed to identify that microbiology PT results were not evaluated or the reviews documented. Cross-refer to D5211 4. The LD's QA reviews failed to identify that the laboratory failed to follow the manufacturer's instructions for performing bacteriology testing. Cross-refer to D5411 5. The LD's QA reviews failed to identify that the laboratory failed to define the acceptable temperature range for room and incubator temperatures which were consistent with the manufacturer's instructions for performing microbiology testing using purchased growth media. Cross-refer to D5413 6. The LD's QA reviews failed to identify that the laboratory's Individualized Quality Control Plan for performing QC on throat and urine culture media was complete, in order to reduce the frequency of QC testing required. Cross-refer to D5445 7. The LD's QA reviews failed to identify that the laboratory failed to perform and document QC on the lot number of "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" (Taxo A discs) currently in use in the laboratory. Cross-refer to D5471 8. The LD's QA reviews failed to identify that the laboratory failed to document corrective action when room and incubator temperatures were out of range. Cross-refer to D5781 9. During an interview on 02/19/2025 at 1:45 PM, the LD confirmed that the laboratory's QA plan was not maintained to identify failures in quality as they occur.