

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0276388	(X3) Date Survey Completed 12/05/2025
Name of Provider or Supplier Pediatrics In Brevard Pa	Street Address, City, State 134 S Woods Dr, Rockledge, FL	
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	An announced CLIA recertification survey was conducted at Pediatrics in Brevard PA on November 5, 2025 to December 5, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5300 493.1250 Condition: Preanalytic Systems D5400 493.1250 Condition: Analytic Systems D6000 493.1403 - Condition: Moderate Complexity Laboratory Director
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to follow manufacturer's instructions for interpreting Dermatophyte Test Medium (DTM) test results within 14 days for 54 (#1- 5, 7 - 12, 14 - 16, 20, 26 - 54, 56 - 64) of 64 (#1 - 64) patients from 06/06/2024 to 10/31/2025. (See D5311)</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5)</p>

Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on record review, and interview, the laboratory failed to follow manufacturer's instructions for interpreting Dermatophyte Test Medium (DTM) test results within 14 days for 54 (#1- 5, 7 - 12, 14 - 16, 20, 26 - 54, 56 - 64) of 64 (#1 - 64) patients from 06/06/2024 to 10/31/2025. Findings: 1. Review of the Instructions for Use for Dermatophyte Test Medium noted, "Media should be examined daily for up to fourteen (14) days." The Instructions for Use for the Dermatophyte Test Medium also noted, "False-positive reactions may result, if interpretations are made beyond 14 days of incubation." 2. Review of the DTM Culture Results Log showed the following patient results were reported after 14 days: Patient #1 - date received 03/06/2024, date completed 04/05/2024 Patient #2 - date received 03/14/2024, date completed 04/15/2024 Patient #3 - date received 04/16/2024, date completed 05/16/2024 Patient #4 - date received 04/17/2024, date completed 05/17/2024 Patient #5 - date received 05/01/2024, date completed 05/31/2024 Patient #7 - date received 05/20/2024, date completed 06/21/2024 Patient #8 - date received 05/23/2024, date completed 06/25/2024 Patient #9 - date received 06/11/2024, date completed 07/11/2024 Patient #10 - date received 07/30/2024, date completed 08/21/2024 Patient #11 - date received 07/30/2024, date completed 08/26/2024 Patient #12 - date received 08/09/2024, date completed 08/26/2024 Patient #14 - date received 08/26/2024, date completed 09/11/2024 Patient #15 - date received 08/29/2024, date completed 09/20/2024 Patient #16 - date received 08/29/2024, date completed 09/20/2024 Patient #20 - date received 09/05/2024, date completed 09/24/2024 Patient #21 - date received 09/12/2024, date completed 09/30/2024 Patient #26 - date received 09/26/2024, date completed 10/11/2024 Patient #27 - date received 10/07/2024, date completed 10/23/2024 Patient #28 - date received 10/25/2024, date completed 11/11/2024 Patient #29 - date received 11/01/2024, date completed 11/21/2024 Patient #30 - date received 11/15/2024, date completed 12/04/2024 Patient #31 - date received 11/15/2024, date completed 12/04/2024 Patient #32 - date received 11/19/2024, date completed 12/04/2024 Patient #33 - date received 12/03/2024, date completed 12/26/2024 Patient #34 - date received 12/03/2024, date completed 12/26/2024 Patient #35 - date received 12/10/2024, date completed 12/31/2024 Patient #36 - date received 12/13/2024, date completed 01/03/2025 Patient #37 - date received 12/16/2024, date completed 01/10/2025 Patient #38 - date received 01/10/2025, date completed 02/10/2025 Patient #39 - date received 01/30/2025, date completed 03/03/2025 Patient #40 - date received 01/30/2025, date completed 03/03/2025 Patient #41 - date received 02/05/2025, date completed 03/06/2025 Patient #42 - date received 02/05/2025, date completed 03/06/2025 Patient #43 - date received 02/07/2025, date completed 03/10/2025 Patient #44 - date received 02/19/2025, date completed 03/21/2025 Patient #45 - date received 02/19/2025, date completed 03/21/2025 Patient #46 - date received 02/19/2025, date completed 03/21/2025 Patient #47 - date received 02/19/2025, date completed 03/21/2025 Patient #48 - date received 02/20/2025, date completed 03/21/2025 Patient #49 - date received 03/13/2025, date completed 04/14/2025 Patient #50 - date received 03/27/2025, date completed 04/29/2025 Patient #51 - date received 03/27/2025, date completed 04/29/2025 Patient #52 - date received 04/01/2025, date completed 04/21/2025 Patient #53 - date received 04/09/2025, date completed 05/06/2025 Patient #54 - date received 04/27/2025, date completed 05/27/2025 Patient #56 - date received 05/29/2025, date completed 06/27/2025 Patient #57 - date received 05/29/2025, date completed 06/30/2025 Patient #58 - date received 07/14/2025, date completed 08/16/2025 Patient #59 - date received 07/17/2025, date completed 08/18/2025 Patient #60 - date received 07

/31/2025, date completed 09/03/2025 Patient #61 - date received 07/31/2025, date completed 09/03/2025 Patient #62 - date received 08/25/2025, date completed 09/25/2025 Patient #63 - date received 09/23/2025, date completed 10/27/2025 Patient #64 - date received 09/30/2025, date completed 10/31/2025 3. During an interview on 11/17/2025 at 11:55 AM, Technical Consultant B stated the received date was the date the cultures were set up. 4. During an interview on 11/17/2025 at 12:20 PM, Technical Consultant B acknowledged patients' DTM test results were reported after 14 days.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete performance specification verification (installation procedure) for the Cell-Dyn Emerald hematology analyzer before testing patients on 01/27/2025 after moving the hematology analyzer to its new location (See D5421); the laboratory failed to perform quality control (QC) measures on the Dermatophyte Test Medium (DTM) agar used to test patients from 05/17/2024 to 05/05/2025 (See D5477); and the laboratory failed to document the quality controls for the Dermatophyte Test Medium (DTM) testing done from 03/16/2024 to 04/27/2025 (See D5481).

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to complete the performance specification verification (installation procedure) for the Cell-Dyn Emerald hematology analyzer before testing patients on 01/27/2025 after moving the hematology analyzer to its new location. Findings: 1. Review of the Cell-Dyn Emerald Operator's Manual noted, "Installation procedures must be repeated if the instrument is moved from the original installation site." 2. Review of the calibration documentation showed the analyzer was calibrated on 11/24/2024 and then on 04/15/2025. No documentation of the performance specification verification which would have included a calibration was found. 3. During an interview on 11/05/2025 at 3:15 PM, Technical Consultant B stated the first day of patient testing after moving

locations was 01/27/2025. 4. During an interview on 11/05/2025 at 4:03 PM, Technical Consultant B acknowledged she did not perform the installation procedure after moving to the new location.

D5477

CONTROL PROCEDURES

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

(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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform quality control (QC) measures on the Dermatophyte Test Medium (DTM) agar used to test patients from 05/17/2024 to 05/05/2025. Findings: 1. Review of the Instructions for Use for the Dermatophyte Test Medium noted "End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements." 2. Review of the procedure titled DTM Microbiological Media Quality Control included instruction on performing the visual check and performing a positive control, a negative control and a control with no growth. The procedure did not include instructions on performing a sterility check. 3. Review of the order invoices showed DTM culture media agar was ordered on 05/17/2024, 08/26/2024, 10/17/2024, and 05/05/2025. 4. Review of the Test Kit Quality Control Log showed the QC passed for Hardy DTM agar received on 05/17/2024 and 09/03/2025. No results of a sterility check performed on the agar was documented. 5. Review of the Test Kit Quality Control Log showed the orders from 10/17/2024, and 05/05/2025 were not documented in the log. 6. Review of the Test Kit Quality Control Log revealed sterility of the DTM agar was not recorded for the media on 05/17/2024, 08/26/2024, 10/17/2024, and 05/05/2025. 7. During an interview on 11/17/2025 at 11:45 AM, Technical Consultant B acknowledged the visual check and QC was not documented for the last two shipments and that she did not do sterility checks on the 4 shipments of DTM agar.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the quality controls (QC) for the Dermatophyte Test Medium (DTM) testing done from 03/16 /2024 to 04/27/2025. Findings: 1. Review of the procedure titled, Laboratory Quality Assurance and Assessment Policy noted, "The laboratory will document all instrument maintenance and quality control. Quality control is run according to, or greater than CLIA (Clinical Laboratory Improvement Amendments) requirements." 2. Review of the Instructions for Use for the Dermatophyte Test Medium noted, "End

users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements." 3. Review of the Instructions for Use for the Dermatophyte Test Medium noted, "if dictated by laboratory quality control procedures or regulations, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or negative reaction." 4. Review of the procedure manual revealed the laboratory did not have a policy on how the laboratory performed their daily controls on days of patient testing for DTM. 5. Review of the DTM Culture Results Log showed there was no documentation of the controls from 03/16/2024 to 04/27/2025. 6. During an interview on 11/17/2025 at 11:50 AM, Technical Consultant B acknowledged they did not have a policy on performing daily QC and that she started to record the daily QC results on 05/08/2025.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure quality laboratory services for all aspects of tests performed. (See D6007); the Laboratory Director failed to ensure testing was performed as required for accurate and reliable results for 54 (#1- 5, 7 - 12, 14 - 16, 20, 26 - 54, 56 - 64) of 64 (#1 - #64) patients from 06/06/2024 to 10/31/2025. (See D6014)

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure quality laboratory services for all aspects of tests performed. Findings: A1. Review of the Instructions for Use for the Dermatophyte Test Medium (DTM), the procedure titled DTM Microbiological Media Quality Control, the order invoices, and the Test Kit Quality Control Log, showed the laboratory failed to perform quality control (QC) measures on the Dermatophyte Test Medium (DTM) agar used to test patients from 05/17/2024 to 05/05/2025. (See D5477) A2. During an interview on 11/17/2025 at 11:45 AM, Technical Consultant B acknowledged the visual check and QC was not documented for the last two shipments and that she did not do sterility checks on the 4 shipments of DTM agar. B1. Review of the procedure titled, Laboratory Quality Assurance and Assessment Policy, the Instructions for Use for the Dermatophyte Test Medium, the procedure manual, and the DTM Culture Results Log showed the laboratory failed to document the quality controls for the Dermatophyte Test Medium (DTM) testing done from 03/16/2024 to 04/27/2025. (See D5481) B2. During an interview on 11/17/2025 at 11:50 AM, Technical Consultant B acknowledged they did

not have a policy on performing daily QC and that she started to record the daily QC results on 05/08/2025.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to ensure testing was performed as required for accurate and reliable results for 54 (#1- 5, 7 - 12, 14 - 16, 20, 26 - 54, 56 - 64) of 64 (#1 - #64) patients from 06/06/2024 to 10/31/2025. Findings: 1. Review of the Instructions for Use for the Dermatophyte Test Medium and the DTM Culture Results Log showed the laboratory failed to follow manufactures instructions for interpreting the Dermatophyte Test Medium (DTM) test results within 14 days for 54 (#1- 5, 7 - 12, 14 - 16, 20, 26 - 54, 56 - 64) of 64 (#1 - 64) patients from 06/06/2024 to 10/31/2025. (See D5311) 2. During an interview on 11 /17/2025 at 11:55 AM, Technical Consultant B stated the received date was the date the cultures were set up. 3. During an interview on 11/17/2025 at 12:20 PM, Technical Consultant B acknowledged patients' DTM test results were reported after 14 days.