

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0903418	<b>(X3) Date Survey Completed</b>  08/21/2023
<b>Name of Provider or Supplier</b>  Personal Care Pediatrics	<b>Street Address, City, State</b>  2964 N Sr 7 Ste 340, Margate, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted on 08/21/2023 found the PERSONAL CARE PEDIATRICS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5403</b>	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to update procedure manual with the culture media used for the throat culture at least since 03/22/2022 to present. Findings included: During the laboratory tour on 08/21/2023 at 2:00 pm, the surveyor found that the laboratory was using Hardy Diagnostic Selective</p>

Strep Agar with lot number 601428P for the throat culture. Review of Quality control log records revealed that the laboratory received the following lots number from Hardy Diagnostic in the following dates: 03/22/2022 lot # 142687, 05/06/2022 lot #502927, 05/20/2022 lot # 145157P, 06/08/2022 lot #144776, 06/30/2022 lot # 2012027, 07/2022 lot # 145157P, 08/15/2022 lot # 508021, 09/13/2022 lot # 146348, 10/03/2022 lot # 147738, 11/17/2022 lot # 147936, 01/10/2023 lot # 148988, 01/11/2023 lot # 520332, 01/14/2023 lot # 150300, 01/24/2023 lot # 150123, 02/01/2023 lot # 520332, 02/23/2023 lot # 150497, 03/06/2023 lot # 150497, 03/27/2023 lot # 150889, 04/25/2023, 151398 lot # 151398, 05/09/2023, lot # 151593, 05/24/2023 lot # 151877, 06/01/2023 lot # 152153, 07/05/2023 lot # 600605P, 07/21/2023 lot # 601193P, 08/02/2023 lot # 601428P. -Review of procedure manual signed by the laboratory director on 03/15/2023, revealed that the media listed was the BD BBL Strep Agar. During an interview on 08/21/2023 at 2:45 PM, the laboratory director confirmed that the procedure manual was not updated with the Selective Strep agar media used in the laboratory at least since 03/22/2022.

**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 record review and interview, the laboratory failed to document the condition of the Selective Streptococcus (Strep) Agar media received in two out of twenty-six batches received from 03/22/2023 to present. The laboratory failed to document the lot numbers for the positive and negative controls used for Selective Strep Agar media evaluation for four out of twenty-six lots received from 03/22/2023 to present. The laboratory failed to document the lot number for the Bacitracin discs used to evaluate six out of twenty-six lots of Selective Strep Agar media received from 03/22/2022 to present. Findings included: -Review of Quality Control records for the Selective Strep Agar culture media revealed that the laboratory received 26 lots from 03/22/2023 to present in the following dates: 03/22/2022 lot # 142687, 05/06/2022 lot #502927, 05/20/2022 lot # 145157P, 06/08/2022 lot #144776, 06/30/2022 lot # 2012027, 07/2022 lot # 145157P, 08/15/2022 lot # 508021, 09/13/2022 lot # 146348, 10/03/2022 lot # 147738, 11/17/2022 lot # 147936, 01/10/2023 lot # 148988, 01/11/2023 lot # 520332, 01/14/2023 lot # 150300, 01/24/2023 lot # 150123, 02/01/2023 lot # 520332, 02/23/2023 lot # 150497, 03/06/2023 lot # 150497, 03/27/2023 lot # 150889, 04/25/2023, 151398 lot # 151398, 05/09/2023, lot # 151593, 05/24/2023 lot # 151877, 06/01/2023 lot # 152153, 07/05/2023 lot # 600605P, 07/21/2023 lot # 601193P, 08/02/2023 lot # 601428P. -The laboratory failed to document the condition for the following lots: 145147 and 601193P. -The laboratory failed to document the lot numbers for the positive and negative strain used to evaluate the capacity to growth or not for the following lots: 150899, 151593, 151877, 152153. -The laboratory failed to document the lot number of the Bacitracin discs used for the evaluation of the Selective Strep Agar media for the following lots:150899, 151593, 151877, 152153, 600605P and 601193P During an interview on 08/21/2023 at 03:00 PM, the laboratory director

confirmed that the laboratory failed to have documentation of the condition of the culture media in the lots of reference, failed to have documentation of the lots of positive and negative controls used to evaluate the lots reference and failed to document the lot number for the Bacitracin discs used for the evaluation in the lots listed above.