

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0185429	<b>(X3) Date Survey Completed</b>  06/30/2022
<b>Name of Provider or Supplier</b>  Tan & Garcia Pediatrics Pc	<b>Street Address, City, State</b>  2020 Good Hope Road, Suite 120, Enola, PA	
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>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records for microbiology media and interview with Site Manager (SM), the laboratory failed to check and document each batch or shipment of microbiology media for physical characteristics from 06/30/2020 to 06/30/2022. Findings Include: 1. On the day of survey 06/30/2022 at 10:45 am, review of microbiology quality control records revealed, the laboratory did not document the visual checks for each batch or shipment for microbiology fro the following media from 06/30/2020 to 06/30/2022. A. 19 of 19 Shipments of Strep selective Agar: - Receiving dates: 07/1/2020, 08/25/2020, 09/30/2020. 12/2/2020, 12/29/2020, 02/05/2020, 03/10/2021, 03/24/2021, 04/28/2021, 06/04/2021, 06/30/2021, 07/22/2021, 09/28/2021, 10/11/2021, 12/26/2021, 01/06/2022, 03/03/2022, 04/04/2022, and 06/13/2022. B. 12 of 12 Shipments of Uricult Agar: - Receiving dates: 07/29/2020, 10/13/2020, 12/10/2020, 01/20/2021, 03/23/2021, 06/24/2021, 07/01/2021, 12/03/2021, 02/07/2022, 03/18/2022, 04/04/2022, and 06/28/2022. 2. The SM confirmed the findings above on 06/30/2022 around 11:30 am.</p>