

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0673684	<b>(X3) Date Survey Completed</b>  04/09/2026
<b>Name of Provider or Supplier</b>  Kenwood Pediatrics Drs Idriss	<b>Street Address, City, State</b>  5301 Westbard Circle Suite #3, Bethesda, MD	
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>D2009</b>	<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 proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory failed to ensure that the identity of the testing personnel (TP) who performed the PT could be determined on attestation statements from six out of six PT events from 2024 through 2025. Findings: 1. The laboratory is enrolled in PT for "Throat Culture ID" and "Urine Culture ID" for the specialty of microbiology. 2. A review of PT records from 2024 through 2025 showed that for six out of six PT events, TP signed their names on the attestation statements, however the signatures were illegible. The names of the TP were not printed on the attestation statements and there was no way to determine which TP performed which portion of the PT by reading the form. 3. During an interview on 04/09/2026 at 2:10 PM the LD confirmed that the laboratory failed to identify the TP who performed the PT.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and competency assessment record review and interview</p>

with the laboratory director (LD), the laboratory failed to establish and follow written policies and procedures to assess the competency of testing personnel (TP) for three out of three years between 2024 and 2026. Findings: 1. A review of the laboratory's written procedure manual showed that the laboratory did not have a procedure for how to perform competency assessments on the TP or the technical consultant. 2. Record review showed that the laboratory documented competency assessments on a two page form. 3. The competency assessment form listed the "tests and/or instruments" for which the TP were evaluated, including "Strep select agar/taxo disk" and "Urinalysis Biplate" in the first column. The form listed the six required procedures for evaluating TP competency in the next columns: "direct observation of test performance", "monitor test result recording & reporting", "review of worksheets, QC, PT & maintenance records", "direct observation of instrument maintenance", "assessment of test performance (PT/blind samples) records", and "assessment of problem-solving skills records". Four of the six listed requirements instructed the reviewer to write the "specific test(s)/records reviewed" and the form stated to "Attach supporting documentation when possible". 4. Record review showed competency forms for three competency assessments performed on two TP from 2024 through 2026. During an interview on 04/09/2026 at 10:53 AM, the LD stated that one of two TP was no longer testing. 5. Competency assessment record review showed that competency assessments were performed for the two TP on 01/17/2024, 01/22/2025, and 01/07/2026. Each of the six required competency assessment procedures for each test were filled in with the date of review and the reviewer's initials. No additional information was noted as required, to document what records were reviewed and there was no supporting documentation attached. 6. During an interview on 04/09/2026 at 2: 10 PM the LD confirmed that the laboratory did not establish or follow written procedures to assess TP competency.

D5471

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

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) 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.

This STANDARD is not met as evidenced by:  
Based on microbiology media quality control (QC) record review and interview with the laboratory director (LD), the laboratory failed to document the identity of the laboratory staff who performed QC checks and the date and the results of the checks on four lot numbers (#) of throat culture media and nine lot # of urine culture media received for throat and urine culture testing in 2025. Findings: 1. The quality assessment portion of the laboratory's individualized quality control plan for both "Strep Select Agar" and "Urine Bi Plate Agar" stated, "All media lot labels are placed in QC Log book and correctly dated and signed." 2. Laboratory staff removed the labels from each sleeve of opened "Selective Strep Agar" and "Blood/MacConkey Biplates" culture media and adhered them to the front and back of the "Selective Strep Agar Plates" or "Blood/MacConkey Biplate" QC forms. The forms included a place for staff to record "No growth, Good Color", "No cracks", and "Date Opened" for each label and were stored in a binder labeled "Plates 2025." 3. A review of seven pages of "Selective Strep Agar Plates" QC forms showed that the laboratory opened

56 sleeves of media from four different lot # of "Selective Strep Agar" for performing throat cultures: lot # 641446, expiration (exp) date 01/05/2025 (one sleeve); lot # 646974, exp date 03/14/2025 (11 sleeves); lot # 648388, exp date 04/03/2025 (33 sleeves); and lot # 648212, exp date 04/15/2025 (11 sleeves). 4. The laboratory staff failed to sign and date 56 out of 56 labels reviewed. There was no documentation of whether the plate QC was acceptable before the media was used, and no way to determine if the laboratory used the media after its expiration date. 5. A review of seven pages of "Blood/MacConkey Biplate" QC forms showed that the laboratory opened 55 sleeves of media from nine different lot # of "Blood/MacConkey Biplates" for performing urine cultures: lot # 643190, exp date 01/22/2025 (nine sleeves); lot # 648210, exp date 04/10/2025 (14 sleeves); lot # 649112P, exp date 04/10/2025 (five sleeves); lot # 651788, exp date 05/14/2025 (eight sleeves); lot # 652251P, exp date 05/28/2025 (two sleeves); lot # 654602P, exp date 06/24/2025 (eight sleeves); lot # 656762, exp date 07/16/2025 (three sleeves); lot # 657158P, exp date 07/29/2025 (four sleeves); and lot # 657749P, exp date 08/13/2025 (two sleeves). 6. The laboratory staff failed to sign and date 55 out of 55 labels reviewed. There was no documentation of whether the plate QC was acceptable before the media was used, and no way to determine if the laboratory used the media after its expiration date. 7. During an interview on 04/09/2026 at 2:10 PM the LD confirmed that the laboratory failed to document microbiology media QC checks, and to include the date of the check and the identity of the laboratory staff who performed the QC.