

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0284855	(X3) Date Survey Completed 03/11/2025
Name of Provider or Supplier Unilab Of Dade Inc	Street Address, City, State 2145 W Davie Blvd Ste 106, Fort Lauderdale, 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 validation survey was conducted at UNILAB OF DADE INC from 03/05/2025 to 03/11/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found out of compliance with the following conditions: -D6033 CFR 493.1409 Technical Consultant. -D6076 CFR 493.1441 Laboratory Director.
D5209	<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 review of laboratory's record and interview with laboratory General Supervisor (GS), the laboratory failed to perform competency evaluation for 2023 for one out of six testing personnel (TP) listed on the FORM CMS-209. Findings included: 1-Review of the annual competency assessment records revealed no competency performed in 2023 for (TP#6) of the testing persons listed in the FORM CMS-209 Laboratory Personnel Report, signed by the Laboratory Director on 02/28 /2025. 2- Review of Laboratory records revealed no corrective action found for the missing competency. 3- Interview with GS on 03/05/2025 at 6:05 PM confirmed that the annual competency assessment was not done for TP#6 in 2023.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

This STANDARD is not met as evidenced by:
 Based on observation, record review and staff interview, the laboratory failed to use controls within the manufacturer's specified expiration for the Beckman Coulter Complete Blood Counter (CBC) DXH 520 since 02/24/2025 and the Beckman Coulter Flow Cytometer Epis XL-MCL since 06/10/2024. Findings included: 1- During the laboratory tour on 03/05/2025 at 10:30 AM, the surveyor found that the laboratory had in use expired CBC DXH 520 controls (with lot number 35256911, 36516912, 372516913) since 02/24/2025 and Flow-Check Fluorospheres (lot number 9435463F) expired since 06/10/2024 and Flow-Set Fluorospheres (lot number 7524073F) expired since 08/07/2024. 2-Review of policy "Reagent use and Documentation" signed by the Laboratory Director (LD) on 07/17/2024, revealed that on section "Procedure" stated "6. Discard all expired reagents. For hazardous substances: see Chemical precautions in the Safety Plan." 3-Review of DXH 500 Series Control manufacturer insert, revealed that controls open vials to be used within 16 days. The laboratory tested 34 patients the following days using expired controls: 02/24/2025, 02/25/2025, 02/27/2025, 02/28/2025 and 03/04/2025. 4-Review of Flow Cytometer Logbook Sheet, revealed the following testing dates after expiration of the Flow Check Fluorospheres: 06/17/2024, 06/29/24, 07/13/2024, 07/31/2024, 08/10 /2024, 09/21/2024, /11/13/2024, 12/20/2024, based on patient report list revealed that the laboratory tested 54 patients in that period. On 03/05/2025 at 5:41 PM, during interview the General Supervisor confirmed that the controls listed above were used after the expiration date.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
 CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
 Based on record review and staff interview, the laboratory failed to ensure that one out of two Technical Consultant for the subspecialty of Bacteriology had a Florida Microbiology Supervisor License from February of 2023 through February of 2025. Refer to D6035

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
 CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for

example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that one of two Technical Consultant (TC) had a Florida Microbiology Supervisor License during the period reviewed from February of 2023 through February of 2025. Findings included: 1- Review of the CMS - 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 02/28/2025 revealed that: a. The LD is also acting as clinical consultant (CC), Technical Consultant (TC)#1 for the specialty of Microbiology in the subspecialty of Bacteriology and a second TC (TC#2) listed for Bacteriology. b. Review of the personnel records for TC#2 revealed that the job description signed on 04/21/2020 the position was for "LABORATORY SUPERVISOR" job description. 2- Review of Form CMS-116 signed by the LD on 02/17/2025, revealed that the laboratory performed the test for Chlamydia trachomatis /Neisseria gonorrhoeae using the Becton Dickinson (BD) Max test in the Bacteriology subspecialty. 3-Review of the JOB DESCRIPTION - DELEGATION OF RESPONSIBILITIES: Laboratory Supervisor Technical/General Supervisor signed on 10/03/2024 by TC#2 and signed by LD on 10/07/2024, the title was "Supervisor". 4- Review of the TC#2 Florida License revealed that TC#2 did not have a current Supervisor License for the specialty of Microbiology. The current license revealed was for a Microbiology Technologist. 5- During interview on 03/05/2025 at approximately 6:00 PM with the laboratory owner and TC#2, they confirmed that TC#2 listed in the 209 and Designee letter does not have a current Florida License as Supervisor for the Specialty of Microbiology and the TC#2 admitted signing Quality Control records and Proficiency testing records for the BD max.

<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on records review and staff interview, the Laboratory Director (LD) failed to ensure that the laboratory had one of two qualified Technical Consultant (TC) for the specialty of Microbiology in the subspecialty of Bacteriology (Refer to D6079); failed to ensure the laboratory did not use expired controls for the Flow Cytometer and the Complete Blood Analyzer (Refer to D6093); failed to ensure the laboratory performed corrective action for the missing annual competency on Testing Personnel #6 in 2023 (Refer to D6102).</p>
<p>D6079</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director failed to delegate duties to a qualified Technical Consultant (TC) for one (TC#2) of the two qualified Technical Consultants for the specialty of Microbiology in the subspecialty of Bacteriology (Refer to D6035).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure the laboratory used controls within the manufacturer's specified expiration for the Beckman Coulter Complete Blood Counter (CBC) DXH 520 since 02/24/2025 and the Beckman Coulter Flow Cytometer Epis XL-MCL since 06/10/2024. (Refer to D5417).</p>

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure there was a corrective action taken and documented when the laboratory failed to perform competency assessments for one (Testing Person #6) of six Testing Personnel in 2023. Refer to D5209.