

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0537572	(X3) Date Survey Completed 06/04/2021
Name of Provider or Supplier Midtown Public Health Office	Street Address, City, State 2400 Wellesley Dr Ne, Albuquerque, NM	
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 onsite recertification survey was conducted on 05/13/2021 and remote review of documentation continued on 05/27/2021. The laboratory was found to be in substantial compliance for the specialities/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed on a WebEx call 06/04/2021 with laboratory staff. The process for submitting the corrections was explained.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the WSLH Proficiency Testing result forms, the laboratory's proficiency testing records, and interview with staff the laboratory failed to document the Laboratory Director or Designee review and evaluation of results for 2 or 4 proficiency testing events in 2020 and 2021. 1. A review of the WSLH Proficiency Testing form reveal "Reviewed By (Lab Director/Designee)". 2. A review of the laboratory's WSLH Proficiency Testing records from 2020 and 2021 revealed the Laboratory Director's or Designee's signature was missing from WSLH PT 2020-BactiReg3 and WSLH PT2021-BactiReg1 results forms. 3. Interview with staff on 05/13/2021 at 11:41 AM confirmed these findings.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of manufacturer's instructions, and interview with the lab coordinator, the laboratory failed to monitor and document the temperature of stored collection kits in patient room #4, which had storage requirements. Findings included: 1. Review of manufacturer's instructions for collection kits included the following storage requirements: Cobas PCR Media Dual Swab Sample Packet, "Store at 15-30C." Remel Microtest M4RT Transport, "Store product in its original container at 2-30C until used." The Thin Prep Pap Test, "Store PreservCyt Solution between 15C (59F) and 30C (86F)." 2. During an observation in patient room #4 on 05/13/2021 at 11:55 am, the surveyor observed the following collection kits on a cart: Cobas PCR Media Dual Swab Sample Packet, Lot #G09755, expiration date 06-30-22 (quantity of 8) Herpes Culture - "Remel Microtest M4RT Transport", Lot # 183491, expiration date 05/13/22 (quantity of 1) The Thin Prep Pap Test, Lot #9352AA, expiration date 12/18/21 (quantity of 1) The room did not include a thermometer for monitoring temperature to ensure all stored supplies were within manufacturer's defined criteria. 3. During an interview on 05/13/2021 at 11:55 am, the lab coordinator stated she brings in the supplies at the beginning of the day then takes those (unused kits) back to the laboratory. She confirmed there was no thermometer for patient room #4. II. Based on direct observation, review of manufacturer's instructions, and interview with staff and Thermo Scientific Technical staff, the laboratory failed to ensure stored Jembec agar plates were per manufacturer's temperature requirements (2-8C). Findings included: 1. During a laboratory tour on 05/13/2021 at 12:21 pm, Jembec agar plates were observed stored in the refrigerator. The box of "Remel Jembec System w/(MOD) Thayer Martin Agar" (Lot #271158, expiration 06/01/2021, received 04/28/21) included a Temperature Limitation (Storage Temperature) symbol of "2C - 8C." Review of Remel Jembec System Thayer Martin Agar (Modified) manufacturer's instructions stated, "Refer to the front of the Remel Technical Manual of Microbiological Media for General Information regarding precautions, product storage ..." The Thermo Scientific "Foreword to the Technical Manual of Microbiological Media" on page 3 for Storage stated, "Store plated media products inside their original packaging (cellophane bag and box) at the appropriate temperature indicated on the product label. In order to prevent dehydration, product should not be stored in close proximity to a fan, or for prolonged periods under a laminar flow hood or in a biological safety cabinet ... Allow products to equilibrate to room temperature prior to use. Media products stored at room temperature for daily use must be stored inside the cellophane bag, away from UV light, not under a laminar flow hood and not for extended periods of time ...To ensure maximum performance and recovery after inoculation, optimal environmental conditions must be followed." 2. During an observation in patient room #4 on 05/13/2021 at 11:55 am, the surveyor observed two Jembec Thayer Martin Agar plates on a metal cart (Lot #271158). During an interview on 05/13/2021 at 11:55 am, the lab coordinator stated she brings two plates from the refrigerator to the patient's room at the beginning of the day. If they are unused then she takes those back to the refrigerator at the end of the day. The manufacturer's instructions did not include returning unused agar plates from room temperature conditions back to 2C-8C conditions as an acceptable practice. Note: According to the laboratory's CMS-116 application the operation, hours were Monday through Friday 8 am to 4:30 pm. 3. During a telephone interview on 06/07/2021 at 1:46 pm, a Thermo Scientific Technical Service Representative stated, that

once the agar (Jembec) is taken out and has "equilibrated to room temperature" it should be used and unused agar should never return to the refrigerator. Word Key: PCR = polymerase chain reaction C = Celsius F = Fahrenheit

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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.

This STANDARD is not met as evidenced by:

Based on direct observation and interview with the Director of Nursing, the laboratory failed to ensure blood collection tubes had not exceeded their expiration date for 14 of 14 tubes. Findings included: 1. During a tour of the phlebotomy room on 05/13/2021 at 9:10 am, there were 14 collection tubes observed with the expiration date "2021-02-28", as follows: BD Vacutainer gold/yellow top blood collection tubes SST - 5.0 ml, Lot #0049781 Further observation included a list of tests posted on the wall completed off the above tubes (when collected) and sent to a reference laboratory, "HIV/RPR combo, HIV + RPR/TPPA combo, RPR/TPPA combo, RPR only, HIV only." 2. During an interview on 05/13/2021 at 9:15 am, the Director of Nursing reviewed the expiration date and confirmed the above findings.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's forms, laboratory temperature logs and interview with staff the laboratory failed to document corrective action when temperatures exceeded the laboratory defined range for 2 of 6 months (random review) in 2020-2021. 1. A review of the laboratory's form "Room Temperature Monitoring Log for the Lab Room" revealed, "Acceptable range for the Lab Room is 68F to 77F". 2. A review of the laboratory's temperature logs April 2021 and December 2020 (random sampling) Room Temperature Monitoring Log for the Lab Room revealed the documented temperature exceeded 68F to 77F on: April 5, 2021; Maximum Temp 80.5F April 6, 2021; Maximum Temp 80.7F April 7, 2021; Maximum Temp 80.7F April 8, 2021; Maximum Temp 80.7F December 7, 2020; Maximum Temp 77.3F December 8, 2020; Maximum Temp 77.6F December 18, 2020; Minimum Temp 67.4 F December 22, 2020; Minimum Temp 63.8F December 29, 2020; Minimum Temp 61.8F 3. Interview with staff on 05/13/2021 at 12:00 PM confirmed the laboratory did not document corrective actions when the temperature exceed the laboratory defined ranges. *Acronyms: Temp=Temperature; F=degrees Fahrenheit