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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D1055630         | <b>(X3) Date Survey Completed</b><br><br>02/15/2022 |
| <b>Name of Provider or Supplier</b><br><br>Thakkar Patel & Avalos Md's Llc   | <b>Street Address, City, State</b><br><br>1009 Sebring Pkwy Suite 101, Sebring, 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>              | An announced CLIA recertification survey was conducted at Thakkar, Patel, & Avalos MDS LLC on 02/11/22 - 02/15/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:   |
| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>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 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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview with Testing Personnel and the new Practice Manager, the laboratory failed to follow the laboratory's policy for the temperature of the water bath for 403 days out of 403 days of testing from November 14, 2019 to February 11, 2022. Findings Included: Review of the "TPA Histology Lab" log revealed an unidentified range of 36-42. Review of policy and procedure titled "Microntomy" signed by the Laboratory Director on 02/08/22 revealed "a. Fill tissue bath with distilled water, heat to 40-45 degrees C [Celsius]." On February 11, 2022 at 11:30 am, Testing Personnel #B stated the range of 36 - 42 was the temperature range for the water bath and confirmed the temperature range did not match the laboratory's policy and procedure. Review of the "TPA Histology Lab" logs revealed the temperature of the water bath had been below the 40 - 45 degrees Celsius range found in the laboratory's policy for 403 days out of 403 days of testing from November 14, 2019 to February 11, 2022 (date of survey). On February 11, 2022 at 11:50 am, the</p> |

new Practice Manager confirmed the water bath temperature range was incorrect and that the temperatures were recorded out of the acceptable range with no corrective action.

**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 observation, record review, and interview with the new Practice Manager and Testing Personnel the laboratory failed to ensure Hematoxylin Stain Solution, Mayer Modified was not expired prior to patient testing from 09/13/21 to 02/10/22. Findings Included: A tour of the laboratory on 02/11/22 at 11:25 AM revealed 1 container of Hematoxylin Stain Solution, Mayer Modified with an expiration of 09/09/21. This solution is used as a counter stain in the immunochemical stain procedures for Alcian Blue Periodic Acid Schiff stain and the Cluster Differentiation (CD) 3 stain. Record review of the patient logs from 09/13/21 to 02/10/2022 revealed 839 Alcian Blue Periodic Acid Schiff stains and 95 CD3 stains were processed using the expired Hematoxylin Stain Solution. On 02/11/2022 at 11:45AM, Testing Personnel #B confirmed that the Hematoxylin Stain Solution, Mayer Modified was expired and Testing Personnel #A stated he was unaware that the Hematoxylin Stain Solution, Mayer Modified was expired. On 02/11/2022 at 11:55 AM, the new Practice Manager stated she did not know that the Hematoxylin Stain Solution, Mayer Modified was expired.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with the new Practice Manager, the laboratory failed to document corrective action when the paraffin temperature for the embedding center was out of range for 462 out of 481 days from November 14, 2019 to February 11, 2022. Findings included: Record review of the "Embedding Center QC" log revealed Paraffin Temp must be within 4 degrees above 56 degrees Celsius. Continued review of the logs revealed the following unacceptable temperatures were documented: 2019 November 14-15, 18-22, 25, and 26: 61 degrees Celsius December 2-6, 9-13, 19-20: 61 degrees Celsius 2020 January 6-10, 13-17, 20-24, 27-30: 61 degrees Celsius February 3-7, 10-12, 14, 17-20, 24: 61 degrees Celsius March 2-6, 9-

13, 16-17: 61 degrees Celsius May 7-8, 11-13, 15, 18-22, 26, 28: 61 degrees Celsius June 1-5, 8-10, 15-19, 22, 26, 29 : 61 degrees Celsius July 1-3, 6-10, 13-17, 20-23, 27-31: 61 degrees Celsius August 3-7, 10-14, 17, 19-20, 24-28: 61 degrees Celsius September 1-4, 9-11, 14-18, 21-25, 28-30: 61 degrees Celsius October 1-2, 5-9, 12-16, 19-23, 27-28: 61 degrees Celsius November 1-6, 9, 16-20, 23-24, 30: 61 degrees Celsius December 1-4, 7-8, 10-11, 14-17: 61 degrees Celsius 2021 January 4-8, 11-15, 18-22, 25: 61 degrees Celsius February 2, 3, 8-11, 15-19, 22-24: 61 degrees Celsius March 1-5, 8-11, 15-19, 22, 31: 61 degrees Celsius April 1-2, 5, 9, 12-16, 21-23, 26-30: 61 degrees Celsius May 3-7, 10-11, 13-14, 17-21, 24-25: 61 degrees Celsius May 26: 62 degrees Celsius May 27-28: 61 degrees Celsius June 1-4, 9-10, 14-18, 28-30: 61 degrees Celsius June 7-8, 11, 22: 62 degrees Celsius July 1-2, 12-14, 16, 19-20: 61 degrees Celsius July 6-9, 15, 21-22: 62 degrees Celsius August 2, 9-12, 16-19: 62 degrees Celsius August 3-6, 13, 23: 61 degrees Celsius August 24-25, 31: 65 degrees Celsius August 30: 66 degrees Celsius September 1-3, 8-9, 13-17, 22, 28: 65 degrees Celsius September 7, 20-21, 23-24, 27, 29-30: 66 degrees Celsius October 1, 4-8, 18-22, 26-27: 66 degrees Celsius October 11-15, 25, 28-29: 65 degrees Celsius November 1-5, 8-10: 66 degrees Celsius November 11-12,18-19, 22-24: 65 degrees Celsius November 29: 64 degrees Celsius December 1-2, 6-10, 13-17, 20-24: 65 degrees Celsius 2022 January 1, 4-7, 12, 18-21, 24-25: 65 degrees Celsius January 10-11, 13, 26, 31: 66 degrees Celsius January 14, 17: 64 degrees Celsius February 1-4, 7-11: 65 degrees Celsius On 02/11/22 at 11:55 a.m., the new Practice Manager reported she was unaware the embedding center temperatures were out of range and no corrective action had been completed.