| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D2119256 | 10/13/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bassan & Bloom Mds Pl | 1701 Ne 164th St Ste 304, North Miami Beach, 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 |
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| **D0000** | A recertification survey conducted on 10/13/2022 found the BASAN & BLOOM MDS PL clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview, the laboratory failed to store Eosin Y Stain Solution and Giemsa Stock Stain Solution according to the manufacturer's instructions. Findings include: During a tour of the laboratory on 10/13/2022 at 10:00 AM, the surveyor found three bottles of one liter each with Eosin Y Stain Solution and two of one liter each of Giemsa Stock Stain Solution stored in an open shelf under the Manual Stainer. Review of Mercedes Scientific safety date sheet for Eosin Y Stain Solution and Giemsa Stock Stain revealed that the storage condition was to "Store in an approved Flammable Liquids storage area". During an interview on 10/13/2022 at 11:30 AM, TP A confirmed that the laboratory failed to store the stains of reference outside of the flammable cabinet. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic |

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| | examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory's procedure manual failed to include instructions for making 70% and 95% alcohol solutions used during the tissue processing on the Sakura Tissue Tek Vacuum Infiltration Processor (VIP) and the 95% solution used in the Hematoxylin and Eosin staining in the manual Stainer. Findings include: Review of the procedure titled, "Tissue processing/Tissue Tek VIP signed on 07/15/2017 by the laboratory director (LD) showed there were no instructions for making of 70% and 95% alcohol solutions. Review of the procedure titled "Procedure for H&E staining" approved by the LD on 07/15/2017, showed there were no instructions for making the 95% alcohol solution. During an interview on 10 /13/2022 at 11:30 AM, TP A confirmed that the laboratory prepared the alcohol solutions of reference and that the instructions were not included in the procedure manual. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on user manual review and interview with testing personnel (TP) A, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the Sakura Tissue Tek Vacuum Infiltration Processor (VIP) E300 for 2 out 2 years reviewed. Findings include: Review of Sakura Tissue Tek VIP user manual revealed an acceptable room temperature range of 10 C to 40 C and humidity requirement not greater than 85 %. No documentation of the room temperature and humidity found for 2021 and 2022. During an interview on 10/13/2022 at 11:30 AM, TP A confirmed that there was no record of room temperature and humidity control check for the rooms where the instrument was located. |