

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031978	(X3) Date Survey Completed 08/25/2021
Name of Provider or Supplier Romagosa Barron Dermatology	Street Address, City, State 2220 Se Ocean Blvd Ste 204, Stuart, 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	A recertification survey was conducted on August 25, 2021. Romagosa Barron Dermatology clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually from 10/04/2019 to 08/25/2021. Findings: The laboratory used peer review to verify the accuracy of the reading and interpretation of H&E stain for their biopsy slides. Review of the Maintenance Logs showed the first date of biopsy testing was 10/04/2021. Review of the laboratory's records showed peer review was not performed on the Dermatopathologist. Review of the histopathology procedure manual signed by the Laboratory Director on 08/06/2021, showed there was no procedure on proficiency testing for the Dermatopathologist.. On 08/25/2021 at 12:20 PM, Testing Personnel G stated the first day of testing was 10/04/2021. On 08/25 /2021 at 3:43 PM, Testing Personnel G stated peer review was not performed on the Dermatopathologist..</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

specimen acceptability and rejection as described in 493.1242. (2) Microscopic 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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's procedure manual failed to include instructions for making the 50% alcohol solution used during their Hematoxylin and Eosin staining process on the Tissue Tek VIP (Vacuum Infiltration Processor) from 10/04/2019 to 08/25/2021. Findings: Review of the procedure titled, "Tissue Tek VIP - Maintenance Schedule", signed on 10/15/2019 by the Laboratory Director, showed there were no instructions for making of the 50% alcohol solution. On 08/25/2021 at 3:39 PM, Testing Personnel G stated they made the 50% alcohol solution and the instructions for making it were not in the procedure.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to document the making of the 50% and 70% alcohol solutions used during their Hematoxylin and Eosin (H&E) staining process on the Tissue Tek VIP (Vacuum Infiltration Processor) from 10/04/2019 to 08/25/2021. Findings: Examination of the Tissue Tek VIP on 08/25/2021 at 12:20 PM, showed the VIP used a 50% and 70% alcohol solution. Review of the "VIP 5 Maintenance Log" showed the laboratory recorded the reagents used for the H&E, the date used, the lot number and the expiration date on the log. The log failed to include the date the reagents were prepared, the lot number of the reagents used and the expiration date of the 50% and 70% alcohol solution the histology technicians made. On 08/25/2021 at 3:39 PM, Testing Personnel G stated they did not document the making of the 50% and 70% alcohol solutions.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must

be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, and interview, the laboratory failed to have a separate negative control slide for Immunohistochemical (IHC) stains for 1 of 5 patients, (#1) Findings: Only the microscopic examination of the IHC stained slides was performed at the laboratory. Observation on 08/25/2021 at 5:00 PM, of the IHC slides for patient #1 showed there was not a separate negative control slide. The Dermatopathologist examines the following IHC stains: Actin Muscle Specific IHC stain, Actin Smooth Muscle IHC stain, Adipophilin IHC stain, BCL-2, (Follicular Lymphoma IHC stain), BCL-6, (Follicular Lymphoma IHC stain), BerEp4 aka Ep-CAM (Epithelial Antigen IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD4 (Cluster of Differentiation 4 T cell Lymphocytic IHC stain), CD5 (Cluster of Differentiation 5 T cell Lymphocytic IHC stain), CD7 (Cluster of Differentiation 7 T cell Lymphocytic IHC stain), CD10 (Cluster of Differentiation 10 Cell Surface Enzyme IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CD30 (Cluster of Differentiation 30 Transmembrane Cytokine Receptor), CD31 (Cluster of Differentiation 31 platelet endothelial cell adhesion molecule-1 IHC stain), CD34 (Cluster of Differentiation 34 progenitor cells IHC stain), CD68 (Cluster of Differentiation 68 Monocytes and Tissue Macrophages IHC stain), CD163 (Cluster of Differentiation 163 monocyte and macrophage IHC stain), CDX2 (Adenocarcinoma IHC stain), CK 5 (Cytokeratin 5 IHC stain), CK 5/6 (Cytokeratin 5 /6 IHC stain), CK7 (Cytokeratin 7 Protein IHC stain), CK20 (Cytokeratin 20 IHC stain), CKIT (CD117) (Cluster of Differentiation 117, stem cell IHC stain), Cyclin D1 (Non-Hodgkin lymphoma IHC stain), Desmin (Smooth Muscle Tumor IHC stain), EBER (ISH) (Epstein-Barr IHC stain), EMA (Epithelial Membrane Antigen IHC stain), Estrogen Receptor IHC stain, Factor XIIIa (Factor XIIIa protein IHC stain), GATA-3 (epithelial and nonepithelial tumors IHC stain), HHV-8 (Herpes Virus Type 8 IHC stain), HMB45 (Anti-Human Melanosome IHC stain), HSV 1 & 2 (Herpes Simplex Virus Type 1 &2 IHC stain), INSM1 (Insulinoma-Associated Protein 1 IHC stain), Kappa (Immunoglobulin Light Chain IHC stain), Keratin OSCAR (Carcinomas IHC stain), Ki-67 (Nuclear Non-histone Protein IHC stain), Lambda (Immunoglobulin Light Chain IHC stain), MART-1 (Melanocytic Marker IHC stain), HSV 1 & 2 (Herpes Simplex Virus Type 1 &2 IHC stain), MLH-1 (MutL Homolog 1 Colorectal Cancer IHC stain), MSH-2 (Melanocyte Stimulation Hormone 2 Tumor Suppressor Gene IHC stain), MSH-6 (Melanocyte Stimulation Hormone 6 Colorectal Cancer and Endometrial Cancer IHC stain), Neurofilament (Neoplastic Cells IHC stain), NKI/C3 (Melanoma IHC stain), P16 (Human Papilloma Virus IHC stain), P40 (polyclonal) (Carcinoma and Lymphoma IHC stain), P-53 (Neoplastic Cells IHC stain), P-63 (Squamous, Urothelial, or Myoepithelial IHC stain), Pancytokeratin (AE1/AE3) (Epithelial IHC stain), PRAME (Preferentially Expressed Antigen in Melanoma IHC stain), PR (Progesterone Receptor IHC stain), PSA (Prostate-Specific Antigen IHC stain), S100 Protein (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), TTF-1 (Thyroid-Transcription Factor 1 IHC stain), and VZV (Varicella Zoster Virus IHC stain). During an interview on 08/25/2021 at 5:00 PM, Testing Personnel G stated there was not a separate negative control slide.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's "Pathology Report" failed to list the name and address of the location where the technical component for the Immunohistochemistry (IHC) Stains were performed for 1 of 5 patient reports examined, (#1). Findings: Review of the "Pathology Report" for patient #1 showed the Dermatopathologist reported results for MART-1 (Melanocytic Marker IHC stain), and SOX-10 (Melanoma IHC stain) IHC slides. Review of the "Pathology Report" showed the report did not indicate where the IHC stains were performed. On 08/25/2021 at 12:20 PM, Testing Personnel G stated the first day of testing was 10/04/2021. On 08/25/2021 at 4:39 PM, Testing Personnel G stated the location where the IHC stains were performed was not mentioned on the report.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Supervisor failed to evaluate the competency for 1 of 1 Dermatopathologist from 10/01/2019 to 08/25/2021. Findings: Review of the Laboratory Personnel Report signed and dated by the Laboratory Director on 8/25/2021 showed the Laboratory Director was also the Technical Supervisor. Review of the Laboratory's competency evaluations showed there were no evaluations on the Dermatopathologist. On 08/25/2021 at 3:39 PM, Testing Personnel G stated that no competency evaluation was ever performed on the Dermatopathologist.