Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2122137	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Precise Diagnostics, Llc	2695 Villa Creek Dr Ste B255, Farmers Branch, TX	

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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 1 of 2 events for testing person 1 (TP-1) in 2021. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing (In House)" (Reviewed by the Laboratory Director on 03/03/2020) revealed the following: "Procedure: In absence of an accredited PT program for pathology, the laboratory instituted its own Quality Control Program for proficiency testing: 1. A pathologist will select 4 cases that have already been signed out for another

pathologist to read. 2. The histologist will pull the slides and re-label them with numbers one through four corresponding to the PT testing sheet. 3. The pathologist will review the slides and circle the correct answer on the PT test sheet. 4. The results will be compared for accuracy and documented." 2. Review of "Pathologist Proficiency Testing" records for Testing Person 1 (TP-1) revealed the following date PT was performed by TP-1 in 2021: 05/2021 The laboratory failed to provide documentation of a second PT event performed by TP-1 in 2021. 3. In an interview on 04/13/2022 at 1:23 p.m. with Testing Person 4 (TP-4), after review of competency, TP-4 confirmed the above findings. II. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 1 of 2 events for testing person 2 (TP-2) in 2021. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing (In House)" (Reviewed by the Laboratory Director on 03/03/2020) revealed the following: "Procedure: In absence of an accredited PT program for pathology, the laboratory instituted its own Quality Control Program for proficiency testing: 1. A pathologist will select 4 cases that have already been signed out for another pathologist to read. 2. The histologist will pull the slides and re-label them with numbers one through four corresponding to the PT testing sheet. 3. The pathologist will review the slides and circle the correct answer on the PT test sheet. 4. The results will be compared for accuracy and documented." 2. Review of "Pathologist Proficiency Testing" records for Testing Person 2 (TP-2) revealed the following date PT was performed by TP-2 in 2021: 01/2021 The laboratory failed to provide documentation of a second PT event performed by TP-2 in 2021. 3. In an interview on 04/13/2022 at 1:23 p.m. with Testing Person 4 (TP-4), after review of competency, TP-4 confirmed the above findings. III. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 1 of 1 event for testing person 1 (TP-1) in 2022. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing (In House)" (Reviewed by the Laboratory Director on 03/03/2020) revealed the following: "Procedure: In absence of an accredited PT program for pathology, the laboratory instituted its own Quality Control Program for proficiency testing: 1. A pathologist will select 4 cases that have already been signed out for another pathologist to read. 2. The histologist will pull the slides and re-label them with numbers one through four corresponding to the PT testing sheet. 3. The pathologist will review the slides and circle the correct answer on the PT test sheet. 4. The results will be compared for accuracy and documented." 2. Review of "Pathologist Proficiency Testing" records for Testing Person 1 (TP-1) revealed the following: "Pathologist Proficiency Testing Date Performed: 04/11/2022 1. a. No pathologic changes b. Candida c. Dermatophyte 2. a. No pathologic changes b. Candida c. Dermatophyte 3. a. No pathologic changes b. Candida c. Dermatophyte 4. a. No pathologic changes b. Candida c. Dermatophyte" The laboratory did not provide any information to evaluate the accuracy of the twice annual accuracy assessment specimens. This included lack of: specimen type, staining characteristics, grossing analysis and any slides or blocks from the samples. 3. In an interview on 04 /13/2022 at 1:23 p.m., Testing Person 4 (TP-4) stated the Laboratory Director "left slides on the table" for the 2022 twice annual accuracy assessment. No slides or documentation was provided. This confirmed the above findings. IV. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for histology specimens for 1 of 1 event for testing person 1 (TP-2) in 2022. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing (In House)" (Reviewed by the Laboratory Director on 03/03/2020) revealed the following: "Procedure: In absence of an accredited PT program for pathology, the laboratory instituted its own Quality

	Control Program for proficiency testing: 1. A pathologist will select 4 cases that have already been signed out for another pathologist to read. 2. The histologist will pull the slides and re-label them with numbers one through four corresponding to the PT testing sheet. 3. The pathologist will review the slides and circle the correct answer on the PT test sheet. 4. The results will be compared for accuracy and documented." 2. Review of "Pathologist Proficiency Testing" records for Testing Person 2 (TP-2) revealed the following: "Pathologist Proficiency Testing Date Performed: 04/11/2022 1. a. No pathologic changes b. Candida c. Dermatophyte 2. a. No pathologic changes b. Candida c. Dermatophyte 3. a. No pathologic changes b. Candida c. Dermatophyte 4. a. No pathologic changes b. Candida c. Dermatophyte" The laboratory did not provide any information to evaluate the accuracy of the twice annual accuracy assessment specimens. This included lack of: specimen type, staining characteristics, grossing analysis and any slides or blocks from the samples. 3. In an interview on 04 /13/2022 at 1:23 p.m., Testing Person 4 (TP-4) stated the Laboratory Director "left slides on the table" for the 2022 twice annual accuracy assessment. No slides or documentation was provided. This confirmed the above findings.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, random review of patient requisitions and confirmed in staff interview, the laboratory failed to ensure patient test records included necessary information to provide accurate interpretation of results. Findings included: 1. Review of laboratory policy titled, "Specimen Collection, Handling, and Accessioning of Tissues" (Reviewed by the Laboratory Director on 04/12/2022) revealed the following: "Specimen Collection: A. Pre-Laboratory handling of specimens: 1. All specimens must be accompanied by a requisition, which should minimally include the following information: a. Patient Name b. Birthdate c. Gender d. Medical practitioner name who obtained the specimen e. Name and address of medical practitioner's office of origin f. Specimen source" 2. Random review of 18 patient requisitions (02/01/2022-03/14/2022) revealed the following information: a. The following 2 of 18 patient requisitions failed to include the address of medical practitioner's office of origin: PD22-0482; PD22-0749 b. The following 1 of 18 patient requisitions failed to include the patient gender per laboratory policy: PD22-0697 c. The following 16 of 18 patient requisitions failed to include the specimen type (Nail, Skin, Soft Tissue, Bone): PP22-0211; PP22-0218; PP22-0226; PP22-0470; PP22-0474; PP22-0482; PP22-0697 PP22-0705; PP22-0707; PP22-0718; PP22-0726;

	PP22-0730; PP22-0749; PP22-0755; PP22-0761 PP22-0790 3. In an interview on 04 /13/2022 at 11:48 a.m. with Testing Person 4 (TP-4), after review of requisitions, TP-4 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, random review of patient test requisitions, and confirmed in interview, the laboratory failed to follow its own written policy for test requisition information for 16 of 18 patient requisitions in 2022 (02/01/2022 through 03/14/2022). 1. Review of laboratory policy titled, "Specimen Collection, Handling, and Accessioning of Tissues" (Reviewed by the Laboratory Director on 04/12/2022) revealed the following: "Specimen Collection: A. Pre-Laboratory handling of specimens: 1. All specimens must be accompanied by a requisition, which should minimally include the following information: a. Patient Name b. Birthdate c. Gender d. Medical practitioner name who obtained the specimen e. Name and address of medical practitioner's office of origin f. Specimen source" 2. Random review of 18 patient requisitions (02/01/2022-03/14/2022) revealed the following information: a. The following 2 of 18 patient requisitions failed to include the address of medical practitioner's office of origin: PD22-0482; PD22-0749 b. The following 1 of 18 patient requisitions failed to include the patient gender per laboratory policy: PD22-0697 c. The following 16 of 18 patient requisitions failed to include the specimen type (Nail, Skin, Soft Tissue, Bone): PP22-0211; PP22-0218; PP22-0226; PP22-0470; PP22-0474; PP22-0482; PP22-0697 PP22-0705; PP22-0707; PP22-0718; PP22-0726; PP22-0730; PP22-0749; PP22-0755; PP22-0761 PP22-0790 3. In an interview on 04 /13/2022 at 11:48 a.m. with Testing Person 4 (TP-4), after review of requisitions, TP-4 confirmed the above findings. This is a repeat deficiency from previous survey conducted on 05/19/2021. II. Based on review of laboratory policy, random review of patient test requisitions, and confirmed in interview, the laboratory failed to follow its own written policy for testing personnel competency verification for 1 of 2 new testing personnel hired in 2022 (03/2022). 1. Review of laboratory policy titled, "Histotechnologist Training for Macroscopic Examinations" (Reviewed by the Laboratory Director on 01/22/2021) revealed the following: "Competency Verification: Dated signatures of the Pathologist are mandatory for authorization of a Histotech to independently perform gross examinations." 2. Review of testing personnel grossing competencies (03/2022) revealed the following competency form not verified by the pathologist: Grossing Competency Assessment: Date Performed: 03 /23/2022 Testing Person: TP-4 Assessor: TP-3 The laboratory failed to follow its own written policy for grossing competency verification for 1 of 2 testing persons in 2022. 3. In an interview on 04/13/2022 at 1:35 p.m. with Testing Person 4 (TP-4), after review of competency, TP-4 confirmed the above findings. III. Based on review of laboratory policy, random review of grossing review forms, and confirmed in interview, the laboratory failed to follow its own written policy for specimen grossing review prior to microscopic examination for 2 of 15 specimen grossing reviews in 2022 (03/01/2022 through 03/31/2022). Findings Included: 1. Review of laboratory policy titled, "Histotechnologist Training for Macroscopic Examinations" (Reviewed

	by the Laboratory Director on 01/22/2021) revealed the following: "Specimen Grossing Review: All specimen blocks and gross descriptions from the requisitions are reviewed and verified to match by a pathologist prior to microscopic examination within 24 hours excluding weekends and holidays. This is documented by the pathologist on the "Specimen Grossing Review Form". 2. Random review of "Specimen Grossing Review Forms" revealed the following 2 of 15 specimen grossing reviews not completed within 24 hours of grossing: a. Accession Numbers (slides): PD22-707 through PD22-732 Date Grossed: 03/01/2022 Pathologist Date Reviewed: 03/23/2022 Time Elapsed: 22 days b. Accession Numbers (slides): PD22-749 through PD22-750 Date Grossed: 03/04/2022 Pathologist Date Reviewed: 03/15 /2022 Time Elapsed: 11 days The laboratory failed to follow its own written policy for specimen grossing review prior to microscopic examination for 2 of 15 specimen grossing reviews in 2022 (03/01/2022 through 03/31/2022). 3. In an interview on 04 /13/2022 at 1:35 p.m. with Testing Person 4 (TP-4), after review of competency, TP-4 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, Tissue-Tek VIP (Vacuum Infiltration Processor) operator's guide, review of the laboratory's environmental monitoring records from 11/2021 through 02/2022, and staff interview, the laboratory failed to monitor and document temperature of the Tissue-Tek VIP 71 of 82 days. Findings: 1. Review of the laboratory's policy "Temperature Monitoring" stated: "OBJECTIVE: Temperature monitoring is an essential factor in accurate laboratory procedures. Temperatures must be monitored to see if they are within acceptable levels. If the temperature is found to be out of the required range, corrective actions must be taken and documented. POLICY: The following areas and equipment require temperature monitoring. All temperatures are recorded in the 'Temperature/Maintenance Records' book Monday through Friday during normal business hours. The laboratory is closed on weekends and holidays unless workload deems it necessary to work. Room Temperature and Humidity is recorded for: Chemical Storage Block and slide storage Microtomy Eye wash station Equipment that requires temperatures to be recorded are: Tissue Processor Embedding station Oven Waterbath [sic] Refrigerator" 2. Review of the Tissue-Tek VIP operator's manual revealed: "Temperature Capabilities ... Paraffin Oven-47C to 72C" 3. A review of the laboratory's environmental monitoring records from 11/2021 through 02/2022 revealed the laboratory had an established an acceptable temperature range for the Tissue Tek VIP of 55C-65C. 4. Further review of the laboratory's environmental monitoring records from 11/2021 through 02/2022 revealed the following 71 of 82 days when the temperature was not monitored or documented as required by the laboratory's written policy for the Tissue Tek VIP: November 2021: 1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 15 December 2021: 1, 2, 3, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 27, 28, 29, 30 January 2022: 3, 4, 5, 6, 7, 10, 11, 12,

13, 14, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 31 February 2022: 1, 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28 5. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. II. Based on review of laboratory policy, review of the laboratory's environmental monitoring records from 11/2021 through 12/2021, and staff interview, the laboratory failed to ensure the temperature of the Boekel Oven was within acceptable range 21 of 40 days. Findings: 1. Review of the laboratory's policy "Temperature Monitoring" stated: "OBJECTIVE: Temperature monitoring is an essential factor in accurate laboratory procedures. Temperatures must be monitored to see if they are within acceptable levels. If the temperature is found to be out of the required range, corrective actions must be taken and documented. POLICY: The following areas and equipment require temperature monitoring. All temperatures are recorded in the 'Temperature/Maintenance Records' book Monday through Friday during normal business hours. The laboratory is closed on weekends and holidays unless workload deems it necessary to work. Room Temperature and Humidity is recorded for: Chemical Storage Block and slide storage Microtomy Eye wash station Equipment that requires temperatures to be recorded are: Tissue Processor Embedding station Oven Waterbath [sic] Refrigerator" 2. A review of the laboratory's environmental monitoring records from 11/2021 through 12/2021 revealed the laboratory had an established an acceptable temperature range for the Boekel Oven (serial number 107905) of 75C-85C. 3. Further review of the laboratory's environmental monitoring records from 11/2021 through 12/2021 revealed the following 21 of 40 days when the temperature was not within the laboratory's acceptable range: Date: 11/30/2020; Temperature: 90 F Date: 12/01/2020; Temperature: 90 F Date: 12/02/2020; Temperature: 90 F Date: 12/03/2020; Temperature: 90 F Date: 12/06/2020; Temperature: 90 F Date: 12/07/2020; Temperature: 90 F Date: 12/08/2020; Temperature: 90 F Date: 12/09/2020; Temperature: 90 F Date: 12/10/2020; Temperature: 90 F Date: 12/13/2020; Temperature: 90 F Date: 12/14/2020; Temperature: 90 F Date: 12/15/2020; Temperature: 90 F Date: 12/16/2020; Temperature: 90 F Date: 12/17/2020; Temperature: 90 F Date: 12/20/2020; Temperature: 90 F Date: 12/21/2020; Temperature: 90 F Date: 12/22/2020; Temperature: 90 F Date: 12/27/2020; Temperature: 90 F Date: 12/28/2020; Temperature: 90 F Date: 12/29/2020; Temperature: 90 F Date: 12/30/2020; Temperature: 90 F 4. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. III. Based on review of laboratory policy, review of the laboratory's environmental monitoring records from 01/2022 through 04/2022, and staff interview, the laboratory failed to monitor and document the temperature of the reagent refrigerator for 38 of 72 days. Findings: 1. Review of the laboratory's policy "Temperature Monitoring" stated: "OBJECTIVE: Temperature monitoring is an essential factor in accurate laboratory procedures. Temperatures must be monitored to see if they are within acceptable levels. If the temperature is found to be out of the required range, corrective actions must be taken and documented. POLICY: The following areas and equipment require temperature monitoring. All temperatures are recorded in the 'Temperature /Maintenance Records' book Monday through Friday during normal business hours. The laboratory is closed on weekends and holidays unless workload deems it necessary to work. Room Temperature and Humidity is recorded for: Chemical Storage Block and slide storage Microtomy Eye wash station Equipment that requires temperatures to be recorded are: Tissue Processor Embedding station Oven Waterbath [sic] Refrigerator" 2. A review of the laboratory's environmental monitoring records from 01/2022 through 04/2022 revealed the laboratory had an established an acceptable temperature range for the Frigidaire refrigerator (serial number BA61619927) of 2C-8C. 3. Further review of the laboratory's environmental monitoring records from 01/2022 through 04/2022 revealed the following 38 of 72

	days when the temperature was not monitored and documented: February 2022: 18, 21, 22, 23, 24, 25, 28 March 2022: 1, 2, 3, 4, 7, 8 ,9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 29, 30, 31 April 2022: 1, 4, 5, 6, 7, 8, 11, 12 4. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. IV. Based on review of laboratory policy, review of the laboratory's environmental monitoring records from 01/2022 through 04/2022, and staff interview, the laboratory failed to monitor and document the temperature of the Tissue Flotation Bath for 72 of 72 days. Findings: 1. Review of the laboratory's policy "Temperature Monitoring" stated: "OBJECTIVE: Temperature monitoring is an essential factor in accurate laboratory procedures. Temperatures must be monitored to see if they are within acceptable levels. If the temperature is found to be out of the required range, corrective actions must be taken and documented. POLICY: The following areas and equipment require temperature monitoring. All temperatures are recorded in the 'Temperature /Maintenance Records' book Monday through Friday during normal business hours. The laboratory is closed on weekends and holidays unless workload deems it necessary to work. Room Temperature and Humidity is recorded for: Chemical Storage Block and slide storage Microtomy Eye wash station Equipment that requires temperatures to be recorded are: Tissue Processor Embedding station Oven Waterbath [sic] Refrigerator" 2. A review of the laboratory's environmental monitoring records from 01/2022 through 04/2022 revealed the laboratory had an established an acceptable temperature range for the Boekel Tissue Flotation Bath (serial number: 03350) of 40C-50C. 3. Further review of the laboratory's environmental monitoring records from 01/2022 through 04/2022 revealed the following 72 of 72 days when the temperature was not monitored and documented: January 2022: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 31 February 2022: 1, 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28 March 2022: 1, 2, 3, 4, 7, 8 ,9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 29, 30, 31 April 2022: 1, 4, 5, 6, 7, 8, 11, 12 4. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. Note: This is a REPEAT deficiency from the initial certification inspection conducted on 03/30/2017.
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 direct observation and confirmed in interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, poured dates, and expiration dates. Findings: 1. During a tour of the microtomy room in the laboratory on 04/13/2022 at 12:20 pm, the surveyor observed the following reagents stored in the refrigerator: 1 plastic container labeled "chemical name: Schiff's; manufacture: Mercedes" The laboratory failed to label the secondary container with the lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. Note: This reagent was poured from a primary container of reagent from the laboratory's bulk supply. 1 plastic container with two labels: First label: "chemical name: 2% Gold Chloride; common: Gold

	Chloride; Manufacture: Stat Lab" Second label: "Gold Chloride; changed 3/30/22; XX (initials)" The laboratory failed to label the secondary container with the reagent lot numbers and expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. Note: This reagent was poured from a primary container of reagent from the laboratory's bulk supply. 1 plastic container with two labels: First label: "chemical name: Schiff's; common: Schiff's Reagent; Manufacture: Platinum Line" Second label: "changed 3/30/22; XX (initials)" The laboratory failed to label the secondary container with the reagent lot numbers, concentration, and expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. Note: This reagent was poured from a primary container of reagent from the laboratory's bulk supply. On the counter the surveyor also observed the following reagents: 1 container with two labels: First label: "3/27/21; XX (initials); changed" Second label: "Chemical name: RDO; common name: Decal; manufacture: Apex" The laboratory failed to label the secondary container with the reagent lot numbers, concentration, and expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During an interview on 04/13/2022 at 12:28 pm, the laboratory manager confirmed the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, poured dates, and expiration dates. Note: This is a REPEAT deficiency from the initial certification inspection conducted on 03/30/2017.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: I. Based on review of the operator's manual, laboratory policy, equipment maintenance records, laboratory records, and confirmed in interview, the laboratory failed to change activated carbon every 6 months as required per laboratory policy for the Tissue Tek VIP (Vacuum Infiltration Processor), Leicia Autostainer XL, and Leicia CV 5030 coverslipper used in processing histopathology specimens. Findings: 1. Review of the Tissue Tek VIP operator's manual revealed: "Periodic Maintenance Fume Control System-Activated Carbon Cartridge Replace the activated cartridge on a regular basis. The recommended schedule is once a month (assuming five processing runs per week); however, this will vary depending upon the frequency and duration of your runs and on the reagents used." 2. Review of the laboratory's "Equipment Maintenance Record" for the Tissue Tek VIP (serial number 48960941) revealed" "Annually PM performed Change activated carbon every 6 months" Further review of the records from May 2021 through March 2022 revealed the last time the activated carbon was changed was on 05/13/2021. The laboratory failed to change the activated carbon filter every six months (due November 2021) as required by the laboratory's policy. 3. Review of the laboratory's "Equipment Maintenance Record" for the Leicia Autostainer XL (serial number XL01041) revealed" "Annually PM performed Change activated carbon every 6 months" Further review of the records from May 2021 through March 2022 revealed the last time the activated carbon was changed was on 05/13/2021. The laboratory failed to change the activated carbon

	filter every six months (due November 2021) as required by the laboratory's policy. 4. Review of the laboratory's "Equipment Maintenance Record" for the Leicia CV 5030 coverslipper (serial number CV5030) revealed" "Annually PM performed by Orion Replace activated carbon filter" Further review of the records from February 2021 through December 2021 revealed no documentation of the activated carbon being replaced. On the log for June 2021 there was a handwritten note next to the "Replace activated carbon filter" that stated "Due June" The laboratory failed to change the activated carbon filter (due June 2021) as required by the laboratory's policy. 5. Review of laboratory records revealed the laboratory performed an annual volume of 4,374 histopathology tests. 6. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. II. Based on review of laboratory policy, equipment maintenance records, and confirmed in interview, the laboratory failed to perform hot water flush on the Tissue Tek VIP (Vacuum Infiltration Processor) as required in their own written policy for 9 of 9 weeks in 2021 (November through December) and 9 of 9 weeks in 2022 (January through February) as required per laboratory policy. Findings: 1. Review of the laboratory's equipment maintenance records for the Tissue Tek VIP revealed a table at the bottom of the log that stated: "Weekly/Monthly Perform hot water flush - indicate with H" 2. Further review of the laboratory's equipment maintenance records for the Tissue Tek VIP from November 2021 through February 2022 revealed the following weeks the hot water flush was not performed as required by the laboratory's policy: November 2021: Weeks 1, 2, 3, 4, 5 December 2021: Weeks 1, 2, 3, 4 January 2022: Weeks 1, 2, 3, 4, 5 February 2022: Weeks 1, 2, 3, 4 3. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. III. Based on review of laboratory policy, equipment maintenance records, and confirmed in interview, the laboratory failed to perform daily maintenance for 42 of 58 days in 2022 (January through April) and failed to perform monthly maintenance for 4 of 4 months in 2022 (January through April) on the Reichert-Jung 2030 Microtome as required per laboratory policy. Findings: 1. Review of the laboratory's equipment maintenance records for the Reichert-Jung 2030 Microtome (serial number 4620857) revealed the following: "Daily Dispose of blade before cleaning Wipe down all surfaces Clean out debris tray Monthly - Indicate with X Oil advancing block mechanism" 2. Further review of the laboratory's equipment maintenance records for the microtome from January 2022 through April 2022 revealed the following days and months daily and monthly maintenance was not performed as required by the laboratory's policy: Daily Maintenance: February 2022: 1, 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28 March 2022: 1, 2, 3, 4, 7, 8 ,9, 10, 11, 14, 15, 16, 17, 18 April 2022: 1, 4, 5, 6, 7, 8, 11, 12 Monthly Maintenance: January, February, March, April 3. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings. IV. Based on review of laboratory policy, equipment maintenance records, and confirmed in interview, the laboratory failed to perform daily maintenance for 32 of 58 days in 2022 (January through April) on the Boekel Tissue Flotation Bath as required per laboratory policy. Findings: 1. Review of the laboratory's equipment maintenance records for the Boekel Tissue Flotation Bath (serial number 03350) revealed the following: "Daily Wipe with Kim Wipe after every block to prevent contamination Wash with hot soapy water after use" 2. Further review of the laboratory's equipment maintenance records for the Tissue Flotation Bath from January 2022 through April 2022 revealed the following days daily maintenance was not performed as required by the laboratory's policy: February 2022: 18 March 2022: 1, 2, 3, 4, 7, 8 ,9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 29, 30, 31 April 2022: 1, 4, 5, 6, 7, 8, 11, 12 3. During an interview on 04/13/2022 at 11:00 am, the laboratory manager confirmed the findings.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Review of the submitted Centers for Medicare and Medicaid (CMS) 209 form, competency assessment records and staff interview, it was revealed the laboratory's technical supervisor failed to evaluate competency assessment for testing personnel for 3 of 3 personnel in 2022. Findings Included: 1. Review of Centers for Medicare and Medicaid (CMS) 209 form submitted at time of survey (4/13/2022) revealed 5 testing people (TP) and 1 Technical Supervisor (TS-1). 2. Review of laboratory competency assessment for 2022 revealed the following competencies not performed by TS-1: a. Grossing Competency Assessment: Date Performed: 03/23/2022 Testing Person: TP-4 Assessor: TP-3 b. Laboratory Competency Assessment: Date Performed: 03/24/2022 Testing Person: TP-4 Assessor: TP-3 c. Laboratory Competency Assessment: Date Performed: 04/08/2022 Testing Person: TP-3 Assessor: TP-4 3. In an interview on 04/13/2022 at 1:35 p.m. with Testing Person 4 (TP-4), after review of competencies, TP-4 confirmed the Technical Supervisor (TS-1) did not perform 3 of 3 competency assessments in 2022 above findings.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50

weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of laboratory policies, Center for Medicare & Medicaid Services (CMS) 209 form, specimen grossing review forms, and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 2 of 15 specimens grossed in 2022 (03/01/2022 through 03/31/2022). Findings Included: 1. Review of laboratory policy titled, "Histotechnologist Training for Macroscopic Examinations" (Reviewed by the Laboratory Director on 01/22/2021) revealed the following: "Specimen Grossing Review: All specimen blocks and gross descriptions from the requisitions are reviewed and verified to match by a pathologist prior to microscopic examination within 24 hours excluding weekends and holidays. This is documented by the pathologist on the "Specimen Grossing Review Form". 2. Review of Center for Medicare & Medicaid Services (CMS) 209 form submitted at time of survey (04/13/2022) listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP-1). The form included one additional general supervisors/testing persons (GS-2/TP-2) who perform reading and interpretation of the slides and also included three additional testing persons (TP-3, TP-4, TP-5), who performed the gross examinations of specimens received from outside clients. The laboratory director/general supervisor/technical supervisor and GS-2/TP-2 were not onsite. TP-3, TP-4 and TP-5 did not qualify as general supervisors or technical supervisors, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 3. Random review of "Specimen Grossing Review Forms" revealed the following 2 of 15 specimen grossing reviews not completed within 24 hours of grossing: a. Accession Numbers (slides): PD22-707 through PD22-732 Date Grossed: 03/01/2022 Pathologist Date Reviewed: 03/23/2022 Time Elapsed: 22 days b. Accession Numbers (slides): PD22-749 through PD22-750 Date Grossed: 03/04/2022 Pathologist Date Reviewed: 03/15/2022 Time Elapsed: 11 days The

	laboratory failed to have documentation of general supervisor review of specimen grossing within 24 hours for 2 of 15 specimens grossed in 2022 (03/01/2022 through 03/31/2022). 4. In an interview on 04/13/2022 at 1:35 p.m. with Testing Person 4 (TP-4), after review of findings, TP-4 confirmed the above findings. This is a repeat deficiency from previous survey conducted on 05/19/2021.