Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1030727	09/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aqua Dermatology Of Florida Pa	13361 Saddle Rd Suite 103, Fort Myers, 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	An onsite unannounced initial survey was conducted 08/31/2023 to 09/15/2023, in conjunction with a complaint survey for complaint number 2023011942, at Riverchase Dermatology. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 General Laboratory Systems - 493.1230 D5400 Analytic Systems - 493.1250 D6076 Laboratory Director -493.1441
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Manager, the laboratory failed to follow manufacturer's instructions to store flammable chemicals in a flammable area for two out of two years (2021 - 2023). Findings Included: A tour of the laboratory on 08/31/2023 at 10:30 AM revealed the following items on a three shelf open unsecured metal rolling cart: a large container with a pour spout labeled "95% Recyl ETOH (ethanol), one open container of 100% Reagent Alcohol, one open and one unopened container of Blue Buffer 8, one unopened container of Xylenes, one opened container of Xylene Substitute (XS-3), an open container of an orange solution labeled 100% Reagent Alcohol ACS Grade Dehydrant, and another liquid filled open container labeled "Xylenes" with the word "Waste" handwritten on the label. Review of the Safety Data Sheet (SDS) for the 100% Reagent Alcohol SDS showed "Flammable liquids Category 2" with storage instructions to keep container in a well-ventilated place in an approved flammable liquids storage area. Review of the Xylene Substitute SDS revealed it was a flammable liquid 3 hazard requiring a fireproof space for storage. Review of the Xylene"SDS revealed it was a flammable

	liquid 3 hazard and required storage in a locked area.. Review of the laboratory's "Storage of Specimens and Reagents Policy" updated and signed by the Laboratory Director on 6/17/22 revealed "Reagents Stored in Flammable Cabinet" included 70%, 95%, and 100% Alcohols, Xylene, Xylene Substitute, and Bluing. On 08/31/23 at 10: 35 AM, the Laboratory Manager confirmed the items were not stored in accordance with the SDS sheets and the laboratory policy. Photographic evidence was obtained.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Manager and Laboratory Director, the laboratory failed to perform personnel competency semi-annually and annually thereafter for seven of seven Testing Personnel for two (2021-2023) of two years reviewed (see D5209), and the laboratory failed to follow the "Extra-departmental case/slide review QA [Quality Assurance]" policy on a quarterly basis for 4 quarters out of 10 quarters reviewed (See D5291).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to perform semi-annual and annual competency assessments for seven out of seven Testing Personnel (#B - #H) for two out of two years (2021 - 2023). Findings Included: Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 08/31/2023 revealed there were seven Testing Personnel (TP). Review of staff records revealed: 1. TP #B was hired on 06/07/21. One competency assessment was documented as performed on 06/25/21. 2. TP #C was hired on 08/23 /21. One competency assessment was documented as performed on 10/30/21. 3. TP #D was hired on 02/01/22. One competency assessment was documented as performed on 02/25/22. 4. TP #E was hired on 10/26/22. One competency assessment was documented as performed on 02/01/23. 5. TP #F was hired on 05/02/22. One competency assessment was documented as performed on 06/27/22. 6. TP #G was hired on 02/20/17. No competency records were found for 2021, 2022, and 2023. 7. TP #H was hired on 05/09/22. One competency assessment was documented as performed on 08/09/22. Record review of the laboratory's procedure titled "Competency Assessment Guidelines [sic]" reviewed by the Laboratory Director on 06 /17/22 revealed "Evaluating and documenting competency of personnel responsible for non-waived testing is required at least semi-annually for the first year. Thereafter,

	competency assessment must be performed at least annually." On 08/31/2023 at 12:55 PM, the Laboratory Manager confirmed competency assessments had not been completed semi-annually and annually. During a telephone interview on 09/08/23 at 11:35 am, the Laboratory Director stated she thought competency assessments were being performed properly.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager and Laboratory Director, the laboratory failed to follow the laboratory's procedure for "Extra-departmental case/slide review QA [Quality Assurance]" on a quarterly basis for 4 (2021 - 4th quarter, 2022-2nd & 4th quarter, 2023-2nd quarter) out of 10 quarters reviewed (2021-3rd & 4th quarter, 2022 - 1st, 2nd, 3rd & 4th quarter, 2023-1st, 2nd, & 3rd quarter). Findings Included: Review of the policy titled "Quality Assurance Policy" reviewed by Laboratory Director on 06/17/22 required an "Extra-departmental case/slide review (QA). This QA required the Pathologist to select 10 cases at random to be reviewed by another physician at a different laboratory; this would be done quarterly to meet Quality Assurance (QA) standards. Record review of the extra-departmental case slide review forms from August of 2021 through August of 2023 revealed QA was not performed for the 4th quarter in 2021, the 2nd & 4th quarter in 2022, and the 2nd quarter in 2023. On 08/31/23 at 01:00 PM, the Laboratory Manager confirmed the laboratory had not completed all the quarterly reviews in accordance with the laboratory's "Quality Assurance Policy." During a telephone interview on 09 /08/23 at 11:20 am, the Laboratory Director confirmed staff failed to pull patient cases on a quarterly basis for QA review.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to follow manufacturer's instructions to check the concentration of the laboratory's recycled alcohol before using it to perform hematoxylin and eosin stains and failed to follow manufacturer's instructions to document pH results in whole numbers (See D5411), failed to ensure reagent containers had preparation and expiration dates (See D5415), failed to ensure expired reagents were not used prior to performing specimen testing (D5417), failed to ensure monthly microtome maintenance documentation (D5429),

	failed to maintain Special Stain and Hematoxylin and Eosin monthly maintenance documentation (D5433), failed to provide complete histopathology quality control documentation for Hematoxylin and Eosin Stain and Special Stain (D5609), and failed to have a Quality Assessment system in place to identify and correct problems within the laboratory (See D5791).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observations, record review, and interviews with the Laboratory Manager and Laboratory Director, the laboratory failed to follow manufacturer's instructions to check the concentration of the laboratory's recycled alcohol before using it to perform hematoxylin and eosin stains on the Tissue Tek Prisma autostainer from 07/17/23 to 09/01/23 and failed to follow manufacturer's instructions to document pH results in whole numbers from 08/01/2021 to 08/31/2023. Findings Included: On 08/31/23 at 11:45 AM, observations revealed the laboratory was recycling alcohol with the PathTrue in the storage room. Record review of the alcohol recycler manual section titled "Using a Hydrometer" revealed "A hydrometer is provided to check the concentration of your recycled alcohol. It is very important to check each batch of alcohol to ensure accurate use of the recycled product...Temperature is another important factor when using a hydrometer. Most standard hydrometers are calibrated at 60 degrees F to obtain an accurate reading....Included is a temperature correction chart for your hydrometer." On 09/01/23 at 02:05 PM, the Laboratory Manager confirmed that the laboratory was taking the temperature of the storage room and using the hydrometer but not documenting the temperature correction for the recycled alcohol. On 09/01/23 at 11:55 AM, observations revealed the laboratory was using pH strips, which results were to be reported in whole numbers, to measure the pH of reconstituted Immunohistochemical (IHC) wash buffer, IHC Low pH Buffer, and IHC High pH buffer. Record review of the "IHC Wash buffer" logs revealed that "IHC Wash Buffer 7.6 +/- 0.1" pH logs results were documented in decimals for 485 days out of 485 days from the Laboratory Manager's hire date of 06/07/21 to 08/31/23. IHC Wash Buffer pH results were reported in decimals on the following days: 08/02/21 - 08/06/21 = 7.6, 08/09/21 - 08/13/21 = 7.6, 08/16/21 - 08/17/21 = 7.6, 08/19/21 - 08/20/21 = 7.6, 08/23/21 - 08/26/21 = 7.6, 08/30/21 - 08/31/21 = 7.6, 09/01/21 - 09/02/21 = 7.6, 09/07/21 - 09/10/21 = 7.6, 09/13/21 = 7.6, 09/15/21 -09/17/21 = 7.6, 09/20/21 - 09/23/21, 09/27/21 - 09/29/21 = 7.6, 10/01/21 = 7.6, 10/04/21 - 10/05/21 = 7.6, 10/07/21 - 10/08/21 = 7.6, 10/11/21 - 10/15/21 = 7.6, 10/18/21 - 10/19/21 = 7.6, 10/21/21 - 10/22/21 = 7.6, 10/25/21 - 10/29/21 = 7.6, 11/01/21 - 11/05/21 = 7.6, 11/08/21 - 11/12/21 = 7.6, 11/15/21 - 11/18/21 = 7.6, 11/22/21 - 11/24/21 = 7.6, 11/29/21 - 11/30/21 = 7.6, 12/01/21 - 12/03/21 = 7.6, 12/06/21 - 12/09/21 = 7.6, 12/13/21 - 12/17/21 = 7.6, 12/20/21 - 12/22/21 = 7.6, 12/27/21 = 7.6, 12/30/21 = 7.6, 01/03/22 - 01/05/22 = 7.6, 01/07/22 = 7.6, 01/10/22 - 01/14/22 = 7.6, 01/17/22 - 01/21/22 = 7.6, 01/24/22 - 01/28/22 = 7.6, 01/31/22 = 7.6, 02/01/22 - 02/04/22 = 7.6, 02/07/22 - 02/11/22 = 7.6, 02/14/22 - 02/18/22 = 7.6, 02/21/22 - 02/25/22 = 7.6, 02/28/22 = 7.6, 03/01/22 - 03/02/22 = 7.6, 03/04/22 = 7.6, 03/07/22 - 03/11/22 = 7.6, 03/14/22 - 03/18/22 = 7.6, 03/21/22 - 03/25/22 = 7.6, 03/28/22 - 03/30/22 = 7.6, 04/01/22 = 7.6, 04/04/22 - 04/08/22 = 7.6, 04/11

	/22 - 04/15/22 = 7.6, 04/19/22 = 7.6, 04/21/22 - 04/22/22 = 7.6, 04/25/22 - 04/29/22 = 7.6, 05/02/22 - 05/05/22 = 7.6, 05/09/22 - 05/12/22 = 7.6 05/16/22 - 05/19/22 = 7.6, 05 /23/22 = 7.6, 05/25/22 - 05/26/22 = 7.6, 05/31/22 = 7.6, 06/01/22 - 06/03/22 = 7.6, 06 /06/22 - 06/10/22 = 7.6, 06/13/22 - 06/17/22 = 7.6, 06/20/22 - 06/24/22 = 7.6, 06/27 /22 - 06/30/22 = 7.6, 07/05/22 = 7.6, 07/07/22 - 07/08/22 = 7.6, 07/11/22 - 07/12/22 = 7.6, 07/18/22 - 07/22/22 = 7.6, 07/25/22 - 07/29/22 = 7.6, 08/01/22 - 08/05/22 = 7.6, 08/09/22 - 08/12/22 = 7.6, 08/15/22 - 08/19/22 = 7.6, 08/22/22 - 08/26/22 = 7.6, 08/29 /22 - 08/31/22 = 7.6, 09/01/22 - 09/02/22 = 7.6, 09/06/22 = 7.6, 09/08/22 - 09/09/22 = 7.6, 09/12/22 - 09/16/22 = 7.6, 09/19/22 - 09/23/22 = 7.6, 09/26/22 = 7.6, 10/10/22 - 10/14/22 = 7.6, 10/17/22 - 10/21/22 = 7.6, 10/24/22 - 10/28/22 = 7.6, 10/31/22 = 7.6, 11/1/22 - 11/04/22 = 7.6, 11/07/22 - 11/11/22 = 7.6, 11/14/22 - 11/18/22 = 7.6, 11/21 /22 - 11/23/22 = 7.6, 11/28/22 - 11/30/22 = 7.6, 12/01/22 - 12/02/22 = 7.6, 12/05/22 - 12/10/22 = 7.6, 12/12/22 - 12/16/22 = 7.6, 12/19/22 - 12/23/22 = 7.6, 12/27/22 - 12/29 /22 = 7.6, 01/03/23 - 01/06/23 = 7.6, 01/09/23 - 01/13/23 = 7.6, 01/16/23 - 01/20/23 = 7.6, 01/23/23 - 01/27/23 = 7.6, 01/30/23 - 01/31/23 = 7.6, 02/01/23 -2/03/23 = 7.6, 02 /06/23 - 02/10/23 = 7.6, 02/13/23 - 02/17/23 = 7.6, 02/20/23 - 02/24/23 = 7.6, 02/27 /23 - 02/28/23 = 7.6, 03/01/23 - 03/03/23 = 7.6, 03/06/23 - 03/10/23 = 7.6, 03/13/23 - 03/17/23 = 7.6, 03/20/23 - 03/24/23 = 7.6, 03/27/23 - 03/31/23 = 7.6, 04/03/23 - 04/07 /23 = 7.6, 04/10/23 - 04/14/23 = 7.6, 04/17/23 - 04/21/23 = 7.6, 04/24/23 - 04/28/23 = 7.6, 05/01/23 - 05/05/23 = 7.6, 05/08/23 - 05/12/23 = 7.6, 05/15/23 - 05/19/23 = 7.6, 05/22/23 - 05/27/23 = 7.6, 05/30/23 = 05/31/23 = 7.6, 06/01/23 - 06/02/23 = 7.6, 06/05 /23 - 06/09/23 = 7.6, 06/12/23 - 06/16/23 = 7.6, 06/19/23 = 7.6, 6/21/23 - 06/23/23 = 7.6, 06/26/23 - 06/30/23 = 7.6, 07/05/23 - 07/07/23 = 7.6, 07/10/23 - 07/14/23 = 7.6, 07/17/23 - 07/21/23 = 7.6, 07/24/23 - 07/28/23 = 7.6, 07/31/23 = 7.6, 08/01/23 - 08/04 /23 = 7.6, 08/08/23 - 08/11/23 = 7.6, 08/14/23 - 08/19/23 = 7.6, 08/21/23 - 08/25/23 = 7.6, 08/28/23 - 08/31/23 = 7.6. Record review of the "IHC Low pH Buffer Test" logs revealed that "IHC Low pH Buffer Test 6.1 +/- 0;1" pH log results were documented in decimals for 149 days out of 154 days from 08/01/21 to 08/31/23. The days the ICH Low pH Buffer Test results were reported in decimals were the following: 08/03 /21, 08/06/21, 08/10/21, 08/16/21, 08/20/21, 08/25/21, 09/01/21, 09/07/21, 09/16/21, 09/20/21, 10/01/2021, 10///21, 10/13/21, 10/21/21, 10/26/21, 11/03/21, 11/09/21, 11 /11/21, 11/12/21, 11/22/21, 11/24/21, 12/02/21, 12/08/21, 12/09/21, 12/20/21, 12/23 /21, 12/29/21, 01/10/22, 01/14/22, 01/19/22, 01/27/22, 01/28/22, 02/07/22, 02/15/22, 02/21/22, 02/23/22, 03/03/22, 03/07/22, 03/11/22, 03/14/22, 03/24/22, 03/25/22, 04/04 /22, 04/06/22, 04/06/22, 04/14/22, 04/21/22, 04/27/22, 04/29/22, 05/04/22, 05/10/22, 05/11/22, 05/12/22, 05/25/22, 06/01/22, 06/08/22, 06/16/22, 06/27/22, 06/29/22, 06/30 /22, 07/11/22, 07/12/22, 07/21/22, 08/02/22, 08/05/22, 08/09/22, 08/19/22, 08/25/22, 08/26/22, 08/31/22, 09/08/22, 09/09/22, 09/20/22, 09/21/22, 09/22/22, 10/11/22, 10/13 /22, 10/21/22, 10/24/22, 10/26/22, 11/01/22, 11/04/22, 11/08/22, 11/09/22, 11/11/22, 11/15/22, 11/21/22, 11/23/22, 11/29/22, 12/02/22, 12/06/22, 12/08/22, 12/13/22, 12/16 /22, 12/21/22, 12/23/22, 01/04/23, 01/10/23, 01/20/23, 01/26/23, 01/31/23, 02/01/23, 02/07/23, 02/15/23, 02/20/23, 02/21/23, 03/01/23, 03/02/23, 03/07/23, 03/08/23, 03/14 /23, 03/15/23, 03/20/23, 03/28/23, 04/03/23, 04/10/23, 04/17/23, 04/18/23, 04/25/23, 04/26/23, 05/01/23, 05/03/23, 05/04/23, 05/08/23, 05/12/23, 05/17/23, 05/23/23, 05/25 /23, 06/01/23, 06/07/23, 06/09/23, 06/16/23, 06/22/23, 06/26/23, 06/29/23, 07/13/23, 07/17/23, 07/18/23, 07/28/23, 08/04/23, 08/08/23, 08/14/23, 08/17/23, 08/19/23, 08/24 /23, 08/29/23 = 6.1 On 09/01/23 at 12:00 pm, Laboratory Manager confirmed the laboratory had been using pH strips that only indicate whole numbers since shortly after she was hired (06/07/2021) and stated the laboratory was estimating the pH value. During a telephone interview on 09/08/23 at 11:35 am, the Laboratory Director stated she was unaware of the reporting discrepancy in the laboratory. Photographic evidence was obtained.

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 with the Laboratory Manager, the laboratory failed to ensure two of two reagent containers used for histopathology staining contained a preparation and expiration date at the time of the survey (08/31 /23). Findings Included: On 08/31/23 at 10:30 AM, observations revealed a large plastic container with a pour spout on the top shelf of a metal rolling cart in the laboratory and another large plastic container with a pour spout in the flammable cabinet. Both containers had a hazard label and had "Recyl ETOH [ethanol]" handwritten on both the label and plastic containers. Both containers had no preparation date and expiration date. Record review of the laboratory's "Storage of Specimens and Reagents Policy" reviewed by the Laboratory Director on 06/17/22 revealed: Any reagents decanted from its original container will have a new expiration date of 6 months after decanting date. Any reagent that does not have an expiration date will be given one, an expiration of 6 months from the opened date. In the case of an unforeseen event that renders the reagents expiration date unknown, the reagent will be assumed expired and disposed of immediately. On 08/31/23 at 10:35 AM, the Laboratory Manager confirmed that both containers were not labeled with the preparation and expiration dates. Photographic evidence was obtained.
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 Laboratory Manager, the laboratory failed to ensure the special stain reagents Borax 5% Aqueous, Nuclear Fast Red Kernechtrot 01%, Potassium Ferrocyanide 2% Aqueous, Harris Hematoxylin with Glacial Acetic Acid, Sodium Chloride Saturated in 80% Reagent Alcohol, and Van Gieson's Solution, used for the subspecialty histopathology testing was not expired prior to performing 52 patient tests from 05/12/23- 8/22/23. Findings Included: A tour of the laboratory on 08/31/23 at 10:55 AM revealed: Borax 5% Aqueous, lot number 086204 with an expiration date of 5/28/23, Harris Hematoxylin with Glacial Acetic Acid , lot number 126511 with an expiration date of 7/1/23, Nuclear Fast Red Kernechtrot 0.1%, lot number is 123997 with an expiration date of 6 /15/23, Potassium Ferrocyanide 2% Aqueous, lot number is 083213 with an expiration date of 5/29/23, Sodium Chloride Saturated in 80% Reagent Alcohol, lot number is 127360 with an expiration date of 7/8/23, and Van Gieson's Solution, lot number is 082979 with an expiration date of 4/29/23. Record review of the laboratory's "Storage of Specimens and Reagents Policy" reviewed by the Laboratory Director on 6/17/22

	revealed "Use of expired reagents is PROHIBITED." Record review of the laboratory's procedure titled "GMS [Grocott Methenamine Silver] Stain" signed by the Laboratory Director on 06/17/22 revealed the solution: Borax 5% Aqueous with an expiration date of 5/28/23 had been used in preparing 2 patient specimens: 1. GMS stain - 06/09/23 2. GMS stain - 07/17/23 Record review of the laboratory's procedure titled "Alkaline Congo Red Method for Amyloid" signed by the Laboratory Director on 06/17/22 revealed the solutions: Harris Hematoxylin with Glacial Acetic Acid with an expiration date of 7/1/23 and Sodium Chloride Saturated in 80% Reagent Alcohol with an expiration date of 7/8/23 had been used in preparing 1 patient specimen: 3. Alkaline Congo Red Method for Amyloid - 08/01/23 Record review of the laboratory's procedure titled "Colloidal Iron Stain" signed by the Laboratory Director on 06/17/22 revealed the solutions: Van Gieson's Solution with an expiration date of 4 /29/23 and Potassium Ferrocyanide 2% Aqueous with an expiration date of 5/29/23 had been used in preparing 44 patient specimens: 4. Colloidal Iron Stain - 05/12/23 5. Colloidal Iron Stain - 05/15/23 6. Colloidal Iron Stain - 05/16/23 7. Colloidal Iron Stain - 05/23/23 8. Colloidal Iron Stain - 05/24/23 9. Colloidal Iron Stain - 05/25/23 10. Colloidal Iron Stain - 05/26/23 11. Colloidal Iron Stain - 06/02/23 12. Colloidal Iron Stain - 06/02/23 13. Colloidal Iron Stain - 06/02/23 14. Colloidal Iron Stain - 06 /05/23 15. Colloidal Iron Stain - 06/05/23 16. Colloidal Iron Stain - 06/05/23 17. Colloidal Iron Stain - 06/06/23 18. Colloidal Iron Stain - 06/08/23 19. Colloidal Iron Stain - 06/15/23 20. Colloidal Iron Stain - 06/15/23 21. Colloidal Iron Stain - 06/16/23 22. Colloidal Iron Stain - 06/21/23 23. Colloidal Iron Stain - 06/21/23 24. Colloidal Iron Stain - 06/21/23 25. Colloidal Iron Stain - 07/10/23 26. Colloidal Iron Stain - 07 /10/23 27. Colloidal Iron Stain - 07/13/23 28. Colloidal Iron Stain - 07/14/23 29. Colloidal Iron Stain - 07/14/23 30. Colloidal Iron Stain - 07/20/23 31. Colloidal Iron Stain - 07/19/23 32. Colloidal Iron Stain - 07/20/23 33. Colloidal Iron Stain - 07/20/23 34. Colloidal Iron Stain - 07/20/23 35. Colloidal Iron Stain - 07/27/23 36. Colloidal Iron Stain - 07/28/23 37. Colloidal Iron Stain - 08/02/23 38. Colloidal Iron Stain - 08 /04/23 39. Colloidal Iron Stain - 08/04/23 40. Colloidal Iron Stain - 08/07/23 41. Colloidal Iron Stain - 08/07/23 42. Colloidal Iron Stain - 08/10/23 43. Colloidal Iron Stain - 08/18/23 44. Colloidal Iron Stain - 08/22/23 45. Colloidal Iron Stain - 08/21/23 46. Colloidal Iron Stain - 08/21/23 47. Colloidal Iron Stain - 08/22/23 Record review of the laboratory's procedure titled "Fontana Masson Stain" signed by the Laboratory Director on 06/17/22 revealed that the solution: Nuclear Fast Red Kernechtrot 0.1% with an expiration date of 6/15/23 had been used in preparing 5 patient specimens: 48. Fontana Masson Stain - 07/12/23 49. Fontana Masson Stain - 07/14/23 50. Fontana Masson Stain - 07/17/23 51. Fontana Masson Stain - 07/19/23 52. Fontana Masson Stain - 08/16/23 On 08/31/23 at 11:05 AM, the Laboratory Manager confirmed the reagents were expired and had been used to test patients' specimens. Photographic evidence was obtained.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review of maintenance records and interview with laboratory staff, the laboratory failed to document monthly microtome maintenance for 5 microtomes for 38 months out of 113 months (2021 - 2023). Findings included: Record review of

	the Leica RM2125 RTS and RM2235 Rotary Microtome user manual revealed both instruments required once a month lubrication of parts. Review of the 5 microtome logs revealed: #1 Leica RM2125 RTS Microtome,serial number 03814, was missing 11 months of maintenance documentation (October, November, and December 2022 and January - August 2023) out of 24 months (August 2021- August 2023). #2 Leica RM2235, serial number 2721/11.2007, was missing 10 months of maintenance documentation (January, April, May, June, July, August 2022 and March, April, July, and August 2023) out of 24 months (August 2021 - August 2023). #3 Leica RM2235, serial number 261/07.2007, was missing 6 months of maintenance documentation (March 2022, November 2022, and April, June, July, and August 2023) out of 24 months (August 2021 - August 2023). #4 Leica RM2235, serial number 3708/02. 2009, was missing 9 months of maintenance documentation (August, September, October, November, December 2022, and February, June, July and August 2023) out of 24 months (August 2021 - August 2023). #5 Leica RM2235, serial number 0068102.2004, was missing 2 months of maintenance documentation (May and July 2023) out of 17 months (March 2022 - August 2023). Record review of the 5 microtome logs revealed the microtome logs were reviewed by the Laboratory Manager for two out of two years (2021 - 2023). On 09/01/23 at 1:50 PM, the Laboratory Manager confirmed the microtome monthly maintenance was not being documented. During a telephone interview on 09/08/23 at 11:30 AM, the Laboratory Director stated she was unaware of the lack of microtome monthly maintenance documentation.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review of maintenance records and interview with laboratory staff, the laboratory failed to document the Special Stain and Hematoxylin and Eosin monthly maintenance for two of two years reviewed (August 2021- August 2023). Findings included: Record review of the "Special Stain Quality Control Form" revealed the monthly maintenance to include "Monthly - Clean Area and Fume Hood Bleach Containers and Lids" had not been documented from August 2021 - August 2023. Record review of the "Hematoxylin and Eosin Stain Line Quality Control form - Sakura Prisma" revealed the monthly maintenance had not been documented for 23 months (August 2021 - July 2023) out of 24 months (August 2021 - August 2023) . The monthly maintenance consisted of: "Bleach Line Flush, Water Containers and Lids" "Wipe out load drawer and Oven" "Wipe outside of Machine and Lid" On 09 /01/23 at 01:00 PM, the Laboratory Manager confirmed the laboratory failed to document the monthly maintenance for the Special Stain and Hematoxylin and Eosin stain. During a telephone interview on 09/08/23 at 11:30 AM, the Laboratory Director stated she was unaware that the Hematoxylin and Eosin and Special Stain monthly maintenance was not being documented.

D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide complete histopathology quality control documentation for Hematoxylin and Eosin Stain and Special Stain (Colloidal Iron, Grocott Methenamine Silver [GMS], Congo Red, Fontana Masson, Giemsa, Prussian Blue, Acid Fast Bacillus, Periodic Acid-Schiff, Elastic, Gram, and Fite stains) for two out of two years (2021- 2023). Findings included: Record review of quality control documentation showed no records of a reagent log with the lot numbers, expiration dates and open dates for the reagents used in the Hematoxylin & Eosin (H & E) stain, Colloidal Iron, Grocott Methenamine Silver Stain, Congo Red, Fontana Masson, Giemsa, Prussian Blue, Acid Fast Bacillus, Periodic Acid-Schiff, Elastic, Gram, and Fite stains On 08/31/23 at 10:33 AM, the Laboratory Manager confirmed reagent logs were not maintained for the stains being performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to have a system in place to identify monitor, assess, and correct problems within the laboratory for two of two years reviewed (2021-2023). Findings included: Review of the laboratory's "Quality Assurance Policy" reviewed and approved by the Laboratory Director on 06/17/22 revealed: "It is the Policy of this laboratory to apply the principles of this QA program to all activities of this laboratory, including pre-analytic, analytic, and post analytic activities. The QA program assures the accurate, reliable, and prompt reporting of the test results, and provides methods to evaluate the effectiveness of its policies and procedures, to identify and correct problems, and to assure the adequacy and competency of the staff." During a telephone interview on 09 /08/23 at 11:15 AM, the Laboratory Manager stated there was no documentation of Quality Assurance (QA) activities.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to have oversight of the laboratory for 2 out of 2 (2021-2023) years reviewed (See D6079).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the Laboratory Director failed failed to delegate laboratory director responsibilities to qualified personnel for two out of two years (2021 - 2023) and failed to ensure overall compliance of the laboratory for two out of two years reviewed (2021 - 2023). Findings Included: Review of the "Delegation of duties to Laboratory Administrator" signed by the Laboratory Director and dated 06/14/22 revealed the laboratory director had delegated laboratory director responsibilities to the Laboratory Manager/Testing Personnel #B who did not qualify to be the technical supervisor or general supervisor. During a telephone interview on 09/13/23 at 11:30 AM, the Laboratory Manager/Testing Personnel B reported she did not know she was not qualified to be delegated laboratory director duties. During a telephone interview on 09/15/23 at 10:15 AM, the Laboratory Director stated she also did not know that the Laboratory Manager did not qualify to be delegated Laboratory Director responsibilities. See D5200: Based on record review and interview with the Laboratory Manager and Laboratory Director, the laboratory failed to perform personnel competency semi-annually and annually thereafter for seven of seven Testing Personnel for two (2021-2023) of two years reviewed (see D5209), and the laboratory failed to follow the "Extra-departmental case/slide review QA [Quality Assurance]" policy on a quarterly basis for 4 quarters out of 10 quarters reviewed (See D5291). See D5400: Based on observation, record review, and interview, the laboratory failed to follow manufacturer's instructions to check the concentration of the laboratory's recycled alcohol before using it to perform hematoxylin and eosin stains and failed to follow manufacturer's instructions to document pH results in whole numbers (See D5411), failed to ensure reagent containers had preparation and expiration dates (See D5415), failed to ensure expired reagents were not used prior to performing specimen testing (D5417), failed to ensure monthly microtome maintenance documentation (D5429), failed to maintain Special Stain and Hematoxylin and Eosin monthly maintenance documentation (D5433), failed to provide complete histopathology quality control documentation for Hematoxylin and Eosin Stain and Special Stain (D5609), and failed to have a Quality Assessment system in place to identify and correct problems within the laboratory (See D5791).