Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2051495	08/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hutchinson Clinic Laboratory Pa	2101 North Waldron, Hutchinson, KS	

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
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 review of the laboratory's maintenance, temperature logs, and quality control records, direct observations, the manufacturers' user manual and package insert instructions, and interviews with Testing Personnel (TP) #1, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 and monitor and evaluate the overall quality of the analytic systems. Findings Include: 1. The laboratory failed to monitor and document refrigerator and room temperatures, which are conditions that are essential to the proper storage of histopathology reagents and accurate and reliable histopathology test system operation. Refer to D5413. 2. The laboratory failed to label the reagents, solutions, and stains located on the histopathology automated stainer with the lot number and preparation and expiration dates. Refer to D5415. 3. The laboratory failed to ensure that reagents, solutions, and supplies were not used when they had exceeded their expiration dates. Refer to D5417. 4. The laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the Leica Bond instrument. Refer to D5429. 5. The laboratory failed to check immunohistochemical stains for positive and negative reactivity each time of use. Refer to D5475.
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: Based on review of the laboratory's temperature logs, manufacturers' package insert instructions, and interview with Testing Personnel (TP) #1, the laboratory failed to monitor and document refrigerator and room temperatures, which are conditions that are essential to the proper storage of histopathology reagents and accurate and reliable histopathology test system operation. Findings Include: 1. Review of the laboratory's temperature logs found daily reagent refrigerator and room temperatures were taken and documented through April 2017. No documentation of reagent refrigerator or room temperatures from May 2017 through the date of survey were found. 2. Review of the manufacturers' package insert instructions for the laboratory's histopathology stains, reagents, and solutions found temperature stability requirements listed for all histopathology stains, reagents, and solutions used by the laboratory. 3. TP #1 stated they were unsure where the temperature logs for May 2017 through the date of survey were. TP #1 further stated that they must not have been done. The interview occurred 08/02/2018 at 11:15 AM.
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 interview with Testing Personnel (TP) #1, the laboratory failed to label the reagents, solutions, and stains located on the histopathology automated stainer with the lot number and preparation and expiration dates. Findings Include: 1. Direct observation of the Leica ST 5020 on the date of survey at 10:33 AM found the reagent, stain, and solution wells were not labeled with the lot numbers and expiration dates of the reagents, stains, and solutions they contained. 2. TP #1 confirmed the wells on the Leica ST 5020 were not labeled to indicate the lot number and preparation and expiration dates of the solutions they contained. The interview occurred 08/02/2018 at 10:37 AM.
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 direct observation, review of the patient test logs, and interview with Testing Personnel (TP) #1, the laboratory failed to ensure that reagents, solutions, and supplies were not used when they had exceeded their expiration dates. Findings Include: 1. Review of patient test logs and direct observation of the laboratory on the date of survey between 10:14 AM and 10:48 AM found the following expired reagents, solutions, and supplies: Acid Alcohol Solution (0.5%) Lot: 37432 Expiration: 01/2018 Patient Tested: 07/03/2018 (New in-dated kit in cabinet but lid seals not broken) Hypochloric Acid Solution (2%) Lot: 39658 Expiration: 07/2018 Stat Lab Green Marking Dye Lot: 34190 Expiration: 10/2016 Sodium Bisulfate Solution Lot: 38055 Expiration: 09/2017 Patient Tested: 06/27/2018 (New in-dated kit in cabinet but lid seals not broken) Potassium Metabisulfate Lot: 38295 Expiration: 09 /2017 Patient Tested: 06/27/2018 Potassium Permanganate Lot: 37498 Expiration: 01 /2018 Patient Tested: 06/27/2018 Alician Blue Solution (pH 2.5) Lot: 35928 Expiration: 02/2017 Aniline Blue Solution Lot: 35427 Expiration: 01/2017 Biebrich Scarlet / Acid Fuchsin Solution Lot: 39205 Expiration: Patient Tested: 06/27/2018 Acetic Acid (1%) Lot: 39467 Expiration: 06/2015 Borax Solution Lot: 35502 Expiration: 01/2017 Patient Tested: 05/03/2018 Sodium Borate Lot: NA Expiration: 06/2018 Methenamin Solution Lot: 41949 Expiration: 07/2018 Silver Nitrate (0.25%) Lot: 41449 Expiration: 06/2018 0.9% Sodium Chloride Irrigation Lot: G107813 Expiration: 05/2016 USP Normal Saline Lot: 1401452 Expiration:02/2016 Histoprep 70% Ethyl (10 bottles) Lot: 330994 Expiration: 04/2018 Histoprep 80% Ethyl (8 bottles) Lot: 325938 Expiration: 04/2018 2. TP #1 confirmed the presence of all reagents, solutions, and supplies listed above. On multiple occassions TP #1 stated the laboratory had in-dated test kits, however, direct observation of the new in-dated test kits found their seals had not been broken. The interviews occurred 08/02/2018 at 10: 14 AM, 10:20 AM, 10:22 AM, 10:27 AM, and 10:48 AM.
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 review of the manufacturer's cleaning and maintenance schedule, the laboratory's Leica Bond maintenance log, and interview with Testing Personnel (TP) #1, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the Leica Bond instrument. Findings Include: 1. Review of the manufacturer's user manual for the Leica Bond found instrument maintenance directives in section 12.1 Cleaning and Maintenance Schedule. Under this section the manufacturer requires daily, weekly, monthly, and as needed maintenance. The weekly maintenance consists of 10 tasks. 2. Review of the laboratory's 2018 maintenance logs found the laboratory failed to perform weekly maintenance for the following weeks: 07/16/2018 05/14 /2018 04/16/2018 03/26/2018 02/26/2018 02/12/2018 01/15/2018 01/02/2018 3. TP #1 confirmed that weekly maintenance was not performed on the Leica Bond on the weeks listed above. TP #1 stated they just weren't able to perform or complete the

	weekly maintenance during those weeks. The interview occurred 08/02/2018 at 10:35 AM.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control log and interview with Testing Personnel (TP) #1, the laboratory failed to check immunohistochemical stains for positive and negative reactivity each time of use. Findings Include: 1. Review of the laboratory's quality control documentation titled "Special Stain Quality Control" from November 2017 through July 2018 found the laboratory only performed and documented a positive control slide with each patient test for the special stains AFB, HP, PASF, FE, Mass, GMS, Retic, and Mel A. An X was occassionally placed in the Control Negative column instead of the Control Positive column. On the following dates patient testing was performed but no quality control was documented: 07/06 /2018 - 6 patients tested for HP, 1 patient tested for PASF 04/02/2018 - 1 patient tested for FE, PASW-WD, Mass, Retic 04/03/2018 - 1 patient tested for Retic 04/25 /2018 - 2 patients tested for HP 04/26/2018 - 1 patient tested for HP 03/22/2018 - 4 patients tested for HP 02/05/2018 - 1 patient tested for GMS, 1 patient tested for AFB 02/02/2018 - 1 patient tested for GMS 12/15/2017 - 3 patients tested for HP 2. TP #1 stated that the laboratory only performs a positive control slide with each patient slide for the special stains listed above and does not perform a negative control slide. TP #1 also explained that when an X was placed in the Control Negative column it indicated that the positive control failed to perform as expected on the control slide. Lastly, TP #1 confirmed the dates listed above were missing quality control documentation but stated there was nothing they could do about it since the pathologists were the ones who performed and failed to document the quality control. The interview occurred 08 /02/2018 at 11:05 AM.