Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D2107905	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Western Montana Clinic Pathology	500 West Broadway, Missoula, MT	

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
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 review of laboratory procedures, laboratory records, and interviews, it was determined that the laboratory failed to establish written policies and procedures to assess the competency of four of four Technical Supervisors who performed cytology microscopic evaluations during 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide a procedure to detail how competency assessment would be performed and documented for four of four Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for four of four Technical Supervisors who performed cytology microscopic evaluations during 2017 and to the date of the survey in 2018. 3. During an interview on 12/3/2018 at 2:25 PM, Cytotechnologist A stated there were no competency assessment records for the Technical Supervisors. 4. During an interview on 12/4/2018 at 1:45 PM, the Laboratory Directory/Technical Supervisor A confirmed these findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic 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 review of 30 laboratory procedures and interview, it was determined that the laboratory failed to establish two written policies and procedures for documenting all quality control procedures performed in the laboratory for 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide a procedure to detail how maintenance and quality control tasks would be performed and documented for one Sakura Tissue Tek Film Coverslipper. 2. The Survey Team requested and the laboratory failed to provide a procedure to detail how maintenance and quality control tasks would be performed and documented for one Cytyc ThinPrep 2000 Processor. 3. During an interview on 12/4/2018 at 2:15 PM, Cytotechnologist A confirmed these findings.
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 and interviews, it was determined that the laboratory failed to ensure that four reagents and solutions were used before their expiration date. Findings include: 1. During an observation of the cytology processing area on 12/4/18 at 8:15 AM, the Survey Team identified four plastic bottles of "Richard-Allan Scientific Cyto-Stain" which had an expiration date of 08/2018. 2. During an interview on 12/4/18 at 9:00 AM, Cytotechnologist A confirmed that the reagents had expired. 3. During an interview on 12/4/2018 at 1:45 PM, the Laboratory Directory /Technical Supervisor A confirmed these findings.
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 the lack of laboratory records and interviews, it was determined that the laboratory failed to ensure that the required maintenance for one Sakura Tissue Tek Film Coverslipper and one Leica ST5020 Automatic Stainer were performed, as specified by the manufacturers, for 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide preventative maintenance records for one Sakura Tissue Tek Film Coverslipper. 2. The Survey Team requested and the laboratory failed to provide preventative maintenance records for one Leica ST5020 Automatic Stainer. 3. During an interview on 12/4/18 at 9:00 AM, Cytotechnologist A confirmed that the laboratory did not perform any preventative maintenance for the Coverslipper or Automatic Stainer. 4. During an interview on 12/4/2018 at 1:45 PM, the Laboratory Directory/Technical Supervisor A confirmed these findings.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview, it was determined that the laboratory failed to document all quality control procedures performed in the laboratory for 2017 and to the date of the survey in 2018. Cross refer to D5403 Findings include: 1. The Survey Team reviewed laboratory records titled SAKURA TISSUE-TEK FILM from December 2017 through November 2018. Six of twelve records failed to document that all quality control tasks in the preparatory area were appropriately performed, documented, and reviewed. Months include: -February 2018 -March 2018 -May 2018 -July 2018 -October 2018 -November 2018 2. The Survey Team reviewed laboratory records titled HOLOGIC THINPREP 2000 PROCESSOR MAINTENANCE from December 2017 through November 2018. Six of twelve records failed to document that all quality control tasks in the preparatory area were appropriately performed, documented, and reviewed. Months include: -December 2017 -February 2018 -March 2018 -April 2018 -June 2018 -November 2018 3. During an interview on 12/4/2018 at 2:15 PM, Cytotechnologist A confirmed these findings.
D9999	