Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2010407	09/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cole Diagnostics	7988 W Marigold St Ste 150, Garden City, ID	

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
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: Based on a record review and an interview with the operation manager, the laboratory failed to document the accuracy of dermatopathology microscopic examinations at least twice a year since the last survey on October 4, 2016. Findings: 1. A document review revealed the laboratory failed to document the accuracy of dermatopathology microscopic examinations performed on frozen biopsy sections at least twice a year since the last survey. 2. An interview on September 5, 2018, at 9:20 AM with the operation manager, confirmed the laboratory failed to document the accuracy of the microscopic examinations at least twice a year.
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 a record review and an interview with the laboratory histotechnician, the

	laboratory failed to monitor and document the room temperature where staining procedures for dermatopathology microscopic examinations are performed since the last survey on October 4, 2016. Findings: 1. A review of temperature record logs revealed the laboratory failed to monitor and document the room temperature in the laboratory where staining procedures for microscopic examinations of frozen section biopsies are performed. 2. An interview on September 5, 2018, at 9:50 AM with the laboratory histotechnician, confirmed the laboratory failed to monitor and document the room temperature of the laboratory since the last survey.
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: D5431 Based on a record a review and an interview with the laboratory director, the laboratory failed to document maintenance activities and function checks for the microscope used for dermatopathology microscopic examinations on frozen section biopsies since the last survey on October 4, 2016. Findings: 1. A review of the procedure manual and documents in the laboratory revealed the laboratory failed to follow and use the microscope maintenance document to record function checks and maintenance activities on the microscope used for examinations of frozen biopsies since the last survey. 2. An interview on September 5, 2018, at 9:45 AM with the laboratory director, confirmed the laboratory failed to document maintenance activities for the microscope.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory histotechnician, the laboratory failed to document the reactivity of a quality control slide for Hematoxylin and Eosin stain each day of patient testing since the last survey on October 4, 2016. Findings: 1. A review of quality control records and a review of the procedure manual, revealed the laboratory failed to document the quality control reaction for Hematoxylin and Eosin stain every day of patient testing as indicated in the procedure manual since the last survey. 2. An interview on September 5, 2018, at 9:45 AM with the laboratory histotechnician, confirmed the laboratory failed to document the reactivity of a quality control slide for Hematoxylin and Eosin stains every day of patient testing.

D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a record review and an interview with the operation manager, the laboratory failed to include the time of specimen receipt into the laboratory and failed to identify the testing personnel who performed microscopic examinations of frozen biopsies since the last survey on October 4, 2016. Findings: 1. A review of patient records and Path Req worksheets for the laboratory, revealed the testing personnel who performed microscopic examinations and interpretation on biopsy specimens was not identified on the patient test records. 2. A review of patient records and Path Req worksheets for the laboratory, revealed the time of specimen collection of biopsy samples was not indicated on the test records. 2. An interview on September 5, 2018, at 9:45 AM, with the operation manager, confirmed the laboratory testing personnel performing microscopic examinations from biopsies and the time of receipt of samples into the laboratory was not identified on the testing records.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a record review of patient reports and an interview with the operation manager, the laboratory failed to indicate the address of the laboratory and the date of dermatopathology microscopic examinations on the patient's final report since the last survey on October 4, 2016. Findings: 1. A review of final patient laboratory test reports in August 2018, revealed the date of test performance and the address of the laboratory performing dermatopathology microscopic examinations failed to be included on the patient's test reports. 2. An interview on September 5, 2018, at 9:45 AM, with the operation manager, confirmed the address of the laboratory and the date of microscopic examination failed to be indicated on patient laboratory reports.