Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2105179	08/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Specialty Laboratories	13530 Michigan Ave Suite Ll1, Dearborn, MI	

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
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 and interview, the laboratory failed to label the chemistry, endocrinology, and toxicology reagents with the preparation and/or expiration date for the reagents used on the Beckman Coulter Access 2 and Au480 chemistry analyzers. Findings include: 1. On August 20, 2018 at 9:20 AM during a tour of the laboratory, the surveyor observed bottled reagents in use that did not have documentation of a preparation and/or expiration date as follows: a. "2% wash WI" b. "Saline" c. "W2 10% NaOH Bleach for A1C" d. "Bleach Sodium (W2) Hypochlorite 10%" e. "Wash 100% CLN-1 100% Wash" f. "H2O" g. "Contrad" h. "Citranox 1/5 dilution" i. "Access 2 wash buffer" 2. During the interview on August 20, 2018 at 9:20 AM, testing personnel #1 as listed on the CMS-209 confirmed the reagent bottles did not contain the preparation and/or expiration dates.
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 observation, record review, and interview, the laboratory failed to indicate the identity of the chemistry prostrate specific antigen (PSA) assay used on the test report as requested in the manufacturer insert for two (#3 and #5) of 16 patient charts audited. Findings include: 1. On August 20, 2018 at 9:20 AM during a tour of the laboratory, the surveyor observed the Beckman Coulter Access 2 chemistry analyzer in use. 2. On August 20, 2018 at approximately 11:00 AM, the procedure manual signed on August 1, 2018 for the PSA procedure revealed no reference to the Beckman Coulter Access Immunoassay Systems Hybritech PSA insert that contained the warning "results reported by the laboratory to the physician must include the identity of the PSA assay used". 3. On August 20, 2018 at 2:56 PM, record review revealed for two (#3 and #5) of 16 patient charts audited the identity of the PSA assay used was not present on the patient's final report in the computer system. 4. During the interview on August 20, 2018 at 2:56 PM, the laboratory director as listed on the CMS-209 confirmed the manufacturer warning was not included in the patients final report.