Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394302	10/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Westfields Hospital Laboratory	535 Hospital Rd, New Richmond, WI	

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 surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory has not verified the accuracy of KOH (potassium hydroxide) testing of skin lesions twice annually. Findings include: 1. Review of PT records showed no evidence of evaluation of accuracy of KOH testing for skin lesions. 2. Interview with the technical consultant on October 25, 2018 at 1:00 PM confirmed the laboratory did not verify the accuracy of KOH testing of skin lesions twice annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's individualized quality control plan

	(IQCP) and procedures, and interview with the technical consultant, the laboratory did not specify the number or type of external liquid controls required for the i-STAT G3+ cartridge. Findings include: 1. Review of the i-STAT IQCP showed no evidence of the number or type of external liquid controls required for the i-STAT G3+ cartridge. 2. Review of the "i-STAT (Non-Coagulation) Procedure" showed no evidence of the number or type of external liquid controls required for the i-STAT G3+ cartridge. 3. Interview with the technical consultant on October 26, 2018 at 10:15 AM confirmed the procedures and the IQCP for the i-STAT do not identify the laboratory's requirement for the type or number of controls needed for the G3+ cartridge.
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 surveyor review of transfusion reaction worksheets and interview with testing personnel, the test report did not indicate the name and address of the laboratory where the testing was performed for two of four transfusion reaction evaluation reports. Findings include: 1. Review of the four most recent Transfusion Reaction Worksheets in the laboratory showed two of the four included the Regions Hospital header on the report. The name and address of the Westfields Hospital laboratory is not on these reports. 2. Interview with testing personnel, staff A, on October 25, 2018 at 1:30 PM confirmed the two reports did not show the name and address of the testing location. Further interview confirmed the worksheet is the final report for the transfusion reaction evaluation and is scanned into the patient's electronic medical record.