Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0433592	10/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hope Clinic For Women	1602 21st St, Granite City, IL	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with testing personnel (TP) #1; the laboratory failed to test proficiency testing (PT) samples in the same manner as it tests patient specimens when analyzing and reporting PT results in the specialty of immunohematology for 4 of 6 PT events reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Laboratory Proficiency Testing Procedure", which stated: "Each quarter, one laboratory technician (on a rotating basis) is instructed to analyze these specimens exactly as they would routine client specimens." 2. Review of American Proficiency Institute (API) immunohematology PT attestation statements for 2016 through 2018 documented PT samples were tested multiple times by different TP for 4 of 6 PT events. PT Event Sample(s) Tested in Duplicate 2016 event 3 RED-12, RED-13 2017 event 3 RED-11, RED-13 2018 event 1 RED-4 2018 event 2 RED-7, RED-8, RED-10 3. Interview with TP#1, at 11:05 am, on 10-31-2018 confirmed that multiple TP ran the same API PT samples for immunohematology prior to submission of results to API and this was not how routine client specimens were tested.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, laboratory records, and interview with testing personnel (TP) #1; the laboratory failed to follow manufacturer's instructions for the storage of EldonCards for Rhesus factor testing for 24 of 24 months reviewed in 2016 through 2018. Findings Include: 1. Review of the manufacturer's instructions for Rhesus factor testing using EldonCards, "Doctor's Kit DKS RhD", states under the heading of "Storage and Stability": "EldonCards should be stored between 5 and 37 degrees Celsius." 2. Direct observation of laboratory testing supplies at 9:30 am, on 10-31-18, identified EldonCards were stored in the laboratory's refrigerator. 3. Review of temperature logs for the laboratory's refrigerator found that the acceptable temperature range was 35-46 degrees Fahrenheit (1.67-7.78 degrees Celsius). 4. Review of the laboratory's refrigerator temperature logs found the temperature of the refrigerator was below 5 degrees Celsius in each of the past 24 months. 5. Review of the laboratory test volume worksheet indicated that 2850 Rh (Rhesus factor) tests had been performed in the past two years (October 2016 through October 2018) when EldonCards had been stored below the manufacturer's acceptable temperature range. 6. On survey date 10-31-2018, at 11:05 am, TP#1 confirmed that EldonCards had been stored in a refrigerator where temperatures were below the manufacturer's acceptable temperature range.