Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0970782	04/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Alamo Women's Reproductive Services	7402 John Smith Drive, Suite 101, San Antonio, TX	

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
D0000	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Alere HemoPoint H2 microcuvettes, surveyor observation of microcuvettes in use in the laboratory on 04/02 /2018, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for storage of the microcuvettes. The findings were: 1. A review of the manufacturer's instructions for the Alere HemoPoint H2 microcuvettes under the section titled "Storage" revealed: "Only remove one Alere HemoPoint H2 microcuvette at a time from the container and then immediately close the lid." 2. Surveyor observation of microcuvettes in use in the laboratory on 04/02/2018 revealed the following container of microcuvettes was in use: HemoPoint H2

	microcuvettes Lot: 1705134 opened: 03/26/2018 The container of microcuvettes was left open from 10:40 am until 11:10 am when it was pointed out to the director of nursing. 3. An interview with the director of nursing on 04/02/2018 at 11:10 am in the laboratory revealed testing personnel had been instructed to close the container after each use. She did not know why the container was left open for 30 minutes. This confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 3 of 6 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's immunohematology proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) revealed the laboratory failed to have documentation of the laboratory director signing 3 of 6 attestation statements. They were: 2016 event 1 2016 event 3 2017 event 1 Note: Someone other than the laboratory director signed his name on 2016 event 1 and 2016 event 3. 2017 event 1 did not have a laboratory signature at all. 2. The laboratory was asked to provide documentation the laboratory director signing the identified attestation statements. No documentation was provided. 3. An interview with the director of nursing on 04/02/2018 at 1000 hours in the break room - after her review of the records- confirmed the findings.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to testing proficiency testing samples the same number of times it tested patient samples. The findings were: 1. A review of the laboratory's American Proficiency Institute's immunohematology proficiency testing records from 2016 (events 1, 2 and 3) and 2017 (events 1, 2, 3) revealed two testing personnel tested each of the proficiency samples and compared their results. 2. The laboratory was asked to provide documentation of have two testing personnel test each patient sample. No documentation was provided. 3. An interview with the director of nursing on 04/02 /2018 at 1000 hours in the break room revealed the proficiency samples were tested more times than patient samples were tested. This confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of the review of the results of 1 of 6 events. The findings were: 1. Based on review of the laboratory's American Proficiency Institute's immunohematology proficiency testing results from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) revealed the laboratory failed to have documentation of the review of results for 1 of 6 events. The event without documentation of review was: 2016 event 1 2. The laboratory was asked to provide documentation of the identified results being reviewed. No documentation was provided. 3. An interview with the director of nursing on 04/02/2018 at 1000 hours in the break room - after her review of the records- confirmed the findings. Note: This is a repeat deficiency from the survey conducted 02/18/2016
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's refrigerator temperature records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the documented refrigerator temperature was outside the laboratory's established acceptable range. The findings were: 1. A review of the laboratory's refrigerator temperature records from 2017 revealed the laboratory's defined acceptable temperature range was 35 - 45F. 2. Further review of the laboratory's temperature records revealed the laboratory documented refrigerator temperatures outside the laboratory's acceptable range: a) January 2017 17 of 17 day out of range b) February 2017 14 of 16 days out of range c) April 2017 17 of 17 days out of range d) May 2017 19 of 19 days out of range e) June 2017 17 of 17 days out of range f) July 2017 16 of 16 days out of range g) August 2017 18 of 18 days out of range h) September 2017 15 of 17 days out of range i) October 2017 25 of 25 days out of range j) November 2017 24 of 24 days out of range k) December 2017 25 of 25 days out of range 3. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 4. An interview with the director of nursing on 04/02/2018 at 1130 hours in the break room - after her review of the records- confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by:

	Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 3 of 5 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 3 of 5 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 03/29/2018) revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 3 of 5 testing personnel to perform testing. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 3 Testing personnel number 4 3. The laboratory was asked to provide documentation of education to qualify the identified testing personnel. No documentation was provided. 4. An interview with the director of nursing on 04/02 /2018 at 1000 hours in the break room - after her review of the records - confirmed the findings.