Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660409	01/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
San Antonio Metropolitan Hlth Dist Lab	2303 Se Military Drive, Bldg 533, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation menu, and staff interview, it was revealed the laboratory failed to have documentation of retaining establishment studies for modified FDA-approved assays performed on the Genprobe Tigris analyzer. The findings were: 1. A review of the laboratory's instrumentation menu revealed the laboratory utilized the Genprobe Tigris analyzer for performing gonorrhea and chlamydia testing from 2010 to June 2017. The laboratory had modified the assay by performing testing on rectal swabs and oral pharyngeal swabs in 2014. 2. Further review of the laboratory's instrumentation menu revealed the laboratory had installed an upgraded version of the Tigris analyzer identified as the

	Panther system in June 2017. Establishment studies for the Panther included a correlation study between the two analyzers which included comparisons of test results for rectal swabs and oral pharyngeal swabs which were still a modification of the FDA-approved assay. The laboratory referred to the studies performed on the Tigris for the rectal and oral pharyngeal swabs to support the use of the swabs on the Panther. 3. The laboratory was asked to provide documentation of the original establishment studies performed on the Tigris analyzer for the rectal swabs and oral pharyngeal swabs to ensure all the necessary studies had been completed. The laboratory was unable to provide the documentation. 4. An interview with the general supervisor on 01/12/2018 at 830 hours in the conference room revealed the laboratory was unable to locate the original establishment studies performed for the rectal and oral pharyngeal swabs. He stated the studies may have been lost when the laboratory moved locations. This confirmed the findings.
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 review of the manufacturer's instructions for the Hologic Aptima Combo 2 Assay, review of the manufacturer's instructions for the Oxford Immunotec T-Spot TB test, review of patient test records, and staff interview, it was revealed the laboratory failed to perform testing only on sample types approved by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the Hologic Aptima Combo 2 Assay (502446 Rev. 003) under the section titled "Limitations" revealed: "The performance of the Aptima Combo 2 Assay has not been evaluated in adolescents less than 14 years of age." 2. A review of patient test records from November 2017 and December 2017 identified the following patients under the age of 14 years whose samples were tested utilizing the Aptima Combo 2 assay: Date Identification number Date of Birth Age 11/06 ****6216-01-001 03/18/2004 13 years 11/06 ****6219-01-001 07/22/2005 12 years 11/08 ****6802-01-001 08/03/2006 11 years 11/08 ****6827-01-001 02/03/2016 1 year 11/14 ****7595-01-001 04/14/2004 13 years 11/14 ****7597-01-001 01/19/2004 13 years 11/14 ****7601-01-001 05/17/2004 13 years 11/14 ****7536-01-001 11/07/2017 1 week 11/14 ****7543-01-001 04/25/2006 11 years 11/14 ****7550-01-001 11/11/2017 3 days 11/16 ****8128-01-001 03/01/2005 12 years 11/16 ****8135-01-001 01/02/2005 12 years 11/16 ****8136-01-001 07/19/2006 11 years 11/28 ****9120-01-001 03/13/2004 13 years 12/04 ****9629-01-001 03/18/2004 13 years 12/04 ****9639-01-001 05/03/2005 12 years 12/04 ****9641-01-001 01/16/2004 13 years 12/04 ****9643-01-001 08/27/2004 13 years 12/04 ****9645-01-001 10/06/2004 13 years 12/04 ****9654-01-001 04/20/2004 13 years 12/04 ****9659-01-001 10/10/2004 13 years 12/05 ****9948-01-001 03/13/2005 12 years 12/05 ****9949-01-001 07/18/2005 12 years 12/07 ****0316-01-001 03/28/2005 12 years 12/12 ****0680-01-001 07/15/2005 12 years 12/12 ****0689-01-001 07/21/2004 13 years 12/12 ****0690-01-001 10/27/2004 13 years 12/14 ****1160-01-001 10/24/2004 13 years 12/14 ****1162-01-001 05/28/2004 13 years 12/19 ****1578-01-001 03/01/2005 12 years 12/19 ****1583-01-001 01/27/2004 13 years 12/19 ****1591-01-001 05/26/2004 13 years 12/19 ****1598-01-001 02/03/2007 10 years 12/21 ****1855-01-001 09/02/2005 12 years 12/21

	****1856-01-001 01/28/2004 13 years 3. A review of the manufacturer's instructions for the Oxford Immunotec T-SPOT TB test (PI-TB-US-V6) under the section titled "Limitations" revealed: "The performance of the T-SPOT. TB test, with or without the use of the T-Cell Xtend reagent, has not bee adequately evaluated with specimens from individuals younger than age 17 years, in pregnant women, and in patients with hemophilia. 4. A review of patient test records from September 2017 and December 2017 revealed the following patients under the age of 17 whose samples were tested utilizing the Oxford Immunotec T-SPOT TB test: Date Identification number Date of Birth Age 09/06 C****412-01 04/26/2013 4 years 09/07 C****559-01 11/19/2013 3 years 09/07 C****571-01 10/29/2007 10 years 09/07 C****573-01 09/03/2009 8 years 09/07 C****574-01 09/25/2006 10 years 09/07 C****578-01 08/04/2010 7 years 09/11 C****909-01 04/02/2007 10 years 09/11 C****911-01 05/09/2005 12 years 09/11 C****912-01 04/29/2003 14 years 09/12 C****030-01 01/11/2005 11 years 09/13 C****141-01 07/27/2009 8 years 09/13 C****142-01 08/29/2010 7 years 09/14 C****322-01 03/06/2003 14 years 09/19 C****739-01 06/19/2004 13 years 09 /20 C****911-01 04/09/2001 16 years 09/20 C****912-01 01/05/2003 14 years 09/21 C****096-01 04/24/2004 13 years 09/21 C****108-01 08/18/2007 10 years 09/26 C****670-01 01/26/2005 12 years 09/28 C****156-01 11/09/2001 16 years 12/06 C****184-01 07/26/2007 10 years 12/06 C****187-01 10/04/2005 12 years 12/12 C****771-01 06/25/2003 14 years 12/13 C****978-01 01/19/2003 14 years 12/14 C****112-01 05/06/2010 6 years 12/14 C****113-01 11/20/2007 7 years 12/14 C****120-01 01/10/2003 14 years 12/14 C****122-01 05/20/2014 3 years 12/14 C****124-01 08/26/2005 12 years 12/21 C****899-01 08/23/2011 6 years 12/21 C****901-01 02/12/2001 16 years 5. The laboratory was asked to provide documentation of having a mechanism in place to ensure providers did not order the Oxford Immunotec T-SPOT TB test on pregnant women or on patients with hemophilia. No documentation was provided. 6. The laboratory was asked to provide documentation of performing establishment studies to support its accepting samples not evaluated by the manufacturers. No documentation was provided. 7. A phone interview with the regulatory department for Oxford Immunotec on 01/19/2018 at 0930 hours in the conference room revealed the company's studies for patients under the age of 17, pregnant women, and patient with hemophilia were not approved by the FDA due to insufficient numbers of study samples. 8. An interview with the general supervisor on 01/11/2018 at 1400 hours in the conference room revealed he was unaware the laboratory was performing testing utilizing the Aptima Combo 2 assay on patients less than 14 years of age. 9. An interview with the general supervisor on 01/12 /2018 at 1530 hours in the conference room revealed the laboratory relied on the ordering physicians to determine which patient samples were tested utilizing the Oxford Immunotec T-SPOT TB test. He stated they knew the correct samples to use and did not have to be monitored to ensure compliance with the manufacturer's instructions. This confirmed the findings.
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 environmental monitoring records and staff interview, it was revealed the laboratory failed to have documentation of performing

	corrective actions when the documented room temperature was outside the laboratory's defined acceptable range. The findings were: 1. A review of the laboratory's environmental monitor records for Immunology Room Number 1116C from July 2017 to September 2017 revealed the laboratory's defined acceptable range for room temperature was 18 to 25C. 2. Further review of the records revealed the following days where the documented room temperature was outside the laboratory's acceptable range: Date Temperature 08/14 33.9C 09/28 17.9C 09/29 17.1C 3. A review of the corrective actions documented for the laboratory' revealed: a) 08/14 Temperature was documented at 27.7C three and one-half hours after original reading No corrective action documented which successfully lowered room temperature into acceptable range. b) 09/28 No corrective actions documented. 17.9C was overwritten and changed to 18.9C c) 09/29 No corrective actions documented. 17.1C was overwritten and changed to 18.1C. 4. An interview with the general supervisor on 01 /12/2018 at 0945 hours in the conference room - after his review of the records- confirmed the findings. KEY C - degrees Celsius
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of reevaluating the competency of testing personnel after an instrument change or new methodology prior to reporting patient results. The findings were: 1. A review of the laboratory's instrumentation records revealed the laboratory changed instruments for performing HIV and Syphilis testing to the BioRad Bio-Plex in July 2017 and changed instrumentation for performing confirmatory HIV testing in November 2016 to the BioRad Geenius Assay. 2. A review of the laboratory's personnel records revealed the following testing personnel (as listed on Form CMS 209) performed HIV and Syphilis testing: Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 3. Further review of the laboratory's personnel records revealed competency assessments were not performed until 12/2017 for HIV and Syphilis performed on the Bio-Plex and 12/2016 for HIV confirmatory testing performed utilizing the Geenius Assay for each of the three personnel identified. 4. An interview with the general supervisor on 01/11/2018 at 1250 hours in the conference room revealed the laboratory did not perform competency assessments after an instrument change on testing personnel before they performed patient testing. This confirmed the findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

	to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of reevaluating the competency of testing personnel after an instrument change prior to reporting patient results. The findings were: 1. A review of the laboratory's instrumentation records revealed the laboratory changed instruments for performing gonorrhea and chlamydia from the Hologic Tigris system to the Hologic Panther system in June 2017. 2. A review of the laboratory's personnel records revealed the following testing personnel (as listed on Form CMS 209) performed testing on the Hologic Panther: Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 3. Further review of the laboratory's personnel records revealed competency assessments were not performed until 12/2017 for each of the three personnel identified. 4. An interview with the general supervisor on 01/11/2018 at 1250 hours in the conference room revealed the laboratory did not perform competency assessments after an instrument change on testing personnel before they performed patient testing. This confirmed the findings.