Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0681831	04/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
James D Kasten Md Inc	278 Benedict Ave Ste 500, Norwalk, OH	

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
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 record review and an interview with the Office Manager (OM), Testing Personnel (TP) #1 failed to attest to two out of two of the Wisconsin State Laboratory of Hygiene (WSLH) wet mount preparation and potassium hydroxide (KOH) proficiency testing (PT) samples for the first PT event in 2017 and the second PT event in 2018 in which PT was performed by TP#1. Findings Include: 1. Review of four out of four of the laboratory's 2017 and 2018 WSLH wet mount preparation and KOH PT records revealed the OM attested as the TP on four out of four PT events (the OM only submitted the reported PT results to the WSLH PT provider), TP#2 participated and attested on two out of two PT events (the second PT event in 2017 and the first PT event in 2018), TP#1 did not provide attestation on two out of two PT events (the first PT event in 2017 and the second PT event in 2018), in which actual PT testing was conducted by TP#1. 2. The Inspector requested the laboratory's current PT policy and procedure and TP#1's 2017 and 2018 PT attestation documentation from the OM. The OM confirmed the laboratory did not have a current PT policy and procedure approved by the Laboratory Director, TP#1 did not provide wet mount preparation and KOH TP attestation for the first PT event in 2017 and the second PT event in 2018, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/23/2019 at 4:10 PM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the laboratory failed to monitor and evaluate the overall quality of the analytic systems for the subspecialties of Bacteriology, Mycology and Parasitology. All patients tested at this laboratory in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to have a written policy and procedure available to and follow by the laboratory personnel for the Cepheid GeneXpert testing for Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT). All patient NG/CT testing performed in this laboratory had the potential to be affected by this deficient practice. (Refer to D5401) 2. The laboratory failed to ensure that the saline utilized for the wet mount preparation testing procedures performed was not used when it had exceeded its expiration date. All patient wet mount preparation testing performed in this laboratory from 03/01/2018 to 04/23/2019 had the potential to be affected by this deficient practice. (Refer to D5417) 3. The laboratory failed to ensure that components of reagent kits of different lot numbers were not interchanged with the BD Affirm test system. All patients tested with the BD Affirm test system in 2017, 2018 and 2019, utilizing reagents and solutions from another kit, had the potential to be affected by this deficient practice. (Refer to D5419) 4. The laboratory failed to perform and document alternative quality control for the wet mount preparation and potassium hydroxide (KOH) testing procedures performed when commercial control materials were not available. All patient wet mount preparation and KOH testing performed in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. (Refer to D5485)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on manual review and an interview with the Office Manager (OM), the laboratory failed to have a written policy and procedure available to and followed by the laboratory personnel for the Cepheid GeneXpert testing for Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT). All patient NG/CT testing performed in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection, did not find a policy and procedure for the Cepheid GeneXpert test system. 2. The Inspector requested the laboratory's Cepheid GeneXpert test system policy and procedure from the OM. The OM stated that she could not locate a

	Cepheid GeneXpert test system policy and procedure and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04 /23/2019 at 4:10 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Office Manager (OM), the laboratory failed to ensure that the saline utilized for the wet mount preparation testing procedures performed was not used when it had exceeded its expiration date. All patient wet mount preparation testing performed in this laboratory from 03/01/2018 to 04/23/2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Provider Performed Microscopy Policy and Procdures", approved, signed and dated by the Laboratory Director on 03/18/2019, found a section "Quality Control" with the following statements: "Saline QC: * Check for expiration date on saline * Do not use if solution appears cloudy * Saline needs to be free of contaminations, after saline bottle opened, only safe for use for 30 days after opened date." QC; quality control 2. Upon direct observation on 04/23/19 at 3:50 PM, the Inspector found the laboratory's only container of saline (Air Life Sterile 0.9 % NaCl; lot ZB1666, expired 2/2018) and revealed the laboratory had been utilizing this expired saline for patient wet mount preparation procedures performed from 03/01/2018 to the date of the inspection, 04/23 /2019. %; percent NaCl; sodium chloride (saline) 3. The Inspector requested the laboratory to provide an indated solution of saline to be used for the wet mount preparation testing procedures from the OM. The OM confirmed the laboratory did not have any other indated saline solution available for use with the wet mount preparation testing procedures performed and was unable to provide the requested product on the date of the inspection. The interview occurred on 04/23/2019 at 3:50 PM.
D5419	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Office Manager (OM), the laboratory failed to ensure that components of reagent kits of different lot numbers were not interchanged with the BD Affirm test system. All patients tested with the BD Affirm test system in 2017, 2018 and 2019, utilizing reagents and solutions from another kit, had the potential to be affected by this deficient practice. Findings Include: 1. Upon direct observation of the BD Affirm testing area in the laboratory on 04/23/2019 at 3:50 PM found two different sets of BD Affirm kit reagents (Lysis and Buffer) with different lot numbers and expiration dates as listed below: BD Lysis Solution Lot expires 8312719 12/26/19 (on counter) 8277804 12/02/19 (on counter)

	BD Buffer Solution 8312721 10/17/19 (on counter) 8296839 10/09/19 (in drawer) 2. The Inspector requested information regarding the use of these reagents from the OM. The OM confirmed the laboratory's practice was to save any remaining reagents after a kits test cartridges were exhausted for the potential use of the reagents with another kit in the event that they ran out of the current kits reagents. The interview occurred on 04/23/2019 at 3:50 PM.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the laboratory failed to perform and document alternative quality control for the wet mount preparation and potassium hydroxide (KOH) testing procedures performed when commercial control materials were not available. All patient wet mount preparation and KOH testing performed in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Provider Performed Microscopy Policy and Procdures", approved, signed and dated by the Laboratory Director on 03/18/2019, found a section "Quality Control" with the following statements: "Traditional quality control for vaginal wet prep test, KOH test... are not required." "Saline QC: * Check for expiration date on saline * Do not use if solution appears cloudy * Saline needs to be free of contaminations, after saline bottle opened, only safe for use for 30 days after opened date." QC; quality control 2. The Inspector requested the laboratory's wet mount preparation and KOH testing quality control policy and procedure and the 2017, 2018 and 2019 quality control documentation from the OM. The OM confirmed the laboratory did not establish and document wet mount preparation and KOH testing quality control policies and procedures in 2017, 2018 and 2019 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/23/2019 at 11:48 AM.
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 record review and an interview with the Office Manager (OM), the laboratory failed to the indicate the address of the laboratory location where the Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT) testing were performed,

	the specimen source for the NG/CT and the BD Affirm testing, the test report date for wet mount preparation, potassium hydroxide (KOH) and BD Affirm testing, and the KOH test result on the final test report. All patients tested in 2017, 2018 and 2019 had the potential to be affected by these deficient practices. Findings Include: 1. Review of three out of three of the laboratory's final test reports for the NG and CT testing performed on the Cepheid GeneXpert Dx System found that the instrument printouts were scanned as a final test report into the corresponding patient electronic medical record (EMR). 1a. Review of three out of three of the laboratory's instrument printouts of the NG and CT test results performed on the Cepheid GeneXpert Dx System did not find the address of the laboratory location where this testing was performed. 2. Review of three out of three of the laboratory's NG/CT and six out of six of the BD Affirm final test reports, provided on the date of the inspection did not find the source of the patients' specimen. 3. Review of five out of five of the laboratory's wet mount preparation and KOH final test reports and six out of six of the BD Affirm final test reports did not find the report date. 4. Review of five out of five of the laboratory's KOH final test reports did not find the results for the KOH testing procedures performed. 5. The OM confirmed the NG/CT instrument printouts were scanned as a final test report into the corresponding patient EMR and did not indicate the address of the laboratory location of where the testing was performed, the NG/CT and the BD Affirm final test reports did not indicate the specimen source, the wet mount preparation, KOH and BD Affirm final test reports did not indicate the report dates and the KOH final test reports did not indicate the KOH results. The interview occurred on 04/23/2019 at 4:05 PM.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to provide technical oversight for the subspecialties Bacteriology, Mycology and Parasitology. All patients tested in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. The TC failed to establish, perform and document an alternative quality control program for the wet mount preparation and potassium hydroxide (KOH) testing procedures performed when commercial control materials were not available. All patients tested at this laboratory in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. (Refer to D6042)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to establish a quality control program for the entire testing processes conducted in the specialties of Bacteriology, Mycology and Parasitology from the initial receipt of the specimen, through sample analysis and to test result reporting. All patients tested at this laboratory in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to have a written policy and procedure available to and follow by the laboratory personnel for the Cepheid GeneXpert testing for Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT). All patient NG/CT testing performed in this laboratory had the potential to be affected by this deficient practice. (Refer to D5401) 2. The laboratory failed to ensure that the saline utilized for the wet mount preparation testing procedures performed was not used when it had exceeded its expiration date. All patient wet mount preparation testing performed in this laboratory from 03/01 /2018 to 04/23/2019 had the potential to be affected by this deficient practice. (Refer to D5417) 3. The laboratory failed to ensure that components of reagent kits of different lot numbers were not interchanged with the BD Affirm test system. All patients tested with the BD Affirm test system in 2017, 2018 and 2019, utilizing reagents and solutions from another kit, had the potential to be affected by this deficient practice. (Refer to D5419) 4. The laboratory failed to perform and document alternative quality control for the wet mount preparation and potassium hydroxide (KOH) testing procedures performed when commercial control materials were not available. All patient wet mount preparation and KOH testing performed in 2017, 2018 and 2019 had the potential to be affected by this deficient practice. (Refer to D5485) 5. The laboratory failed to the indicate the address of the laboratory location where the Neisseria Gonorrhea (NG) and Chlamydia Trachomatis (CT) testing were performed, the specimen source for the NG/CT and the BD Affirm testing, the test report date for wet mount preparation, potassium hydroxide (KOH) and BD Affirm testing, and the KOH test result on the final test report. All patients tested in 2017, 2018 and 2019 had the potential to be affected by these deficient practices. (Refer to D5805)