Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2103364	11/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Thomas P Lenns, Llc	89 Main Street, Hilton Head Island, SC	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: During an onsite recertification survey on 11/26/2018, based on review of CASPER Report 155D and proficency testing results from College of American Pathologists (CAP), the laboratory failed to successfully participate in proficiency testing for the sub-specialty of routine chemistry, the analyte high densilty lipoproteins (HDL), for two consecutive proficiency events (2018, Events A and B). See D2087.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: During an onsite recertification survey performed on 11/26/2018, based on the CASPER 155D report review and onsite proficiency testing results review from CAP, the laboratory failed to attain a satisfactory score of at least 80% for HDL for two consecutive proficiency testing events. Findings include: 1. The CASPER 155D report revealed the following scores for HDL: a. 2018, Event A: 0% b. 2018, Event B: 40% 2. The scores were confirmed by onsite review of the graded CAP results. Scores less than 80% for this analyte indicates unsatisfactory performance. A failure of this analyte for two consecutive or two out of three consecutive testing events is scored as unsuccessful.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: During an onsite recertification survey on 11/26/2018, based on the Access 2 chemistry analyzer operator's manual review, laboratory humidity record review, and staff interview, it was determined that the laboratory failed to maintain acceptable humidity recordings for a total of 86 of 528 days reviewed from December 2016 to November 2018. Findings include: 1. Review of the Access 2 chemistry analyzer operator's manual revealed that performance is only guaranteed from the instrument in an operating environment of 20 to 80 percent humidity. 2. Review of the laboratory's humidity recordings revealed that the laboratory reached less than 20 percent humidity for a total of 86 of 528 days reviewed from December 2016 to November 2018. There was no corrective action for the out of range humidity recordings during this time period available for review. 3. Testing personnel confirmed during an onsite interview on 11/26/2018 at 3:30pm that the laboratory had failed to maintain proper humidity recordings.