Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315173	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Realm And Family Practice	2120 Merchant'S Row, Suite 2, Germantown, TN	

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 review of the laboratory's proficiency testing attestation statements for chemistry group 2 2016 events two and three and interview with the laboratory director, the laboratory director failed to sign the attestation statements for 2016 events one and three. The findings include: 1. Review of the laboratory's proficiency testing attestation statements for 2016 chemistry group 2 events two and three revealed no laboratory director signature on the attestation statements. 2. Interview with the laboratory director on August 14, 2018 at 2 pm confirmed the laboratory director failed to sign the attestation statements for 2016 events two and three.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2017 and 2018 and interview with the laboratory director, the laboratory failed to retain all proficiency testing records for at least two years in 2017. The findings include: 1. Review of the laboratory's 2017 proficiency testing records revealed no retention of attestation statements for the following events: 2017 event one core chemistry, 2017 event one miscellaneous chemistry, 2017 event two core chemistry, 2017 event two

	miscellaneous chemistry, 2017 event three core chemistry. 2. Review of the laboratory's 2017 proficiency testing records revealed no retention of the data submission reports for the following events: 2017 event one core chemistry, 2017 event one miscellaneous chemistry, 2017 event two core chemistry. 3. Interview with the laboratory director on August 14, 2018 at 2:00 pm confirmed the laboratory failed to retain all proficiency testing records in 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's thyroid stimulating hormone (TSH) quality control (QC) records for February 2018, the patient test log for TSH for February 2018, the laboratory's quality assessment monitoring form for February 2018, and interview with the laboratory director the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with TSH quality control in February 2018 with patient testing reported. The findings include: 1. Observation of the laboratory on August 14, 2018 at 8:45 am revealed the Qualigen FastPak instrument on the counter in use for patient testing. 2. Review of the laboratory's quality control records for the TSH analyte for February 2018 revealed that the level one control was out of range (high) on February 9, 2018, with no corrective action or repeat testing of quality control. No signature of the laboratory director on the form used for recording quality control was noted. 3. Review of the patient TSH test log revealed three patients were reported from the previous acceptable quality control performed on 2.1.2018 to the next acceptable quality control performed on 02.15.2018 as follows: Patient #1 performed on 02.02.18, patient #2 performed on 2.8.18, patient #3 performed on 02.12.18. 4. Review of the quality assessment monitoring form for February 2018 revealed the following: Each QC Event, two levels of quality control were tested and were within acceptable ranges before patients were tested--Marked as yes, form signed by the laboratory director, with no corrective action documented. 5. Interview with the laboratory director on August 14, 2018 at 2:00 pm confirmed the laboratory's quality assessment process failed to identify and correct problems with TSH quality control when it did not detect that quality control was unacceptable in February 2018 with three patients reported between successful QC events.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing performance evaluation reports for 2016 and 2017 and interview with the laboratory director, the laboratory director failed to ensure all proficiency testing reports are reviewed to evaluate the laboratory's performance and identify problems that require corrective action. The findings include: 1. Review of the laboratory's proficiency testing evaluation report for 2016 chemistry group 2 second event revealed an unacceptable score for the thyroid stimulating hormone for sample number CH-08 with no corrective action performed and no review of report by laboratory director. 2. Review of the laboratory's proficiency testing evaluation report for 2016 chemistry group 2 third event revealed unacceptable scores for the Vitamin D analyte and non-graded scores for the TSH analyte with no signature of the laboratory director on either the performance evaluation report or the corrective action performed for the vitamin D analyte. No evaluation of the non-graded score for TSH was performed. 3. Review of the laboratory's performance evaluation reports for 2017 chemistry core event one, 2017 chemistry core event two, and 2017 core event three revealed no review signatures. 4. Review of the laboratory's 2017 chemistry miscellaneous 2nd event corrective action for PSA and testosterone revealed no review of corrective action by the laboratory director. 5. Interview with the laboratory director on August 14, 2018 at 2 pm confirmed that the laboratory director failed to ensure all proficiency testing reports are reviewed to evaluate laboratory performance when the laboratory director did not review proficiency testing performance evaluation reports and corrective actions in 2016 and 2017.