Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315173	05/27/2021
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medical Services Laboratory Personnel Report (Form CMS-209), proficiency testing records, patient test records, and interviews with the laboratory director and lead testing person, proficiency testing samples were not performed by personnel who routinely perform patient testing in 2018, 2019, 2020, and 2021. The findings include: 1. Review of the Form CMS-209 revealed three personnel who perform patient testing for Testosterone, Prostate Specific Antigen (PSA) and Thyroid Stimulating Hormone (TSH). 2. Review of the laboratory's proficiency testing records revealed eleven of twelve proficiency testing events were performed by the lead testing person. 3. Review of patient test records from May 2019, September 2020, and March 2021 revealed patient testing performed by testing personnel other than the lead testing person. 4. Interviews with the laboratory director and lead testing person on May 27, 2021 at 10:30am confirmed the lead testing person performed eleven of twelve proficiency testing events. Other testing personnel perform patient testing. Proficiency testing was not rotated among personnel who routinely perform patient testing in 2018, 2019, 2020 and 2021.
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 proficiency testing records and interviews with the laboratory director and lead testing person, the laboratory failed to test proficiency testing samples the same number of times as patient samples in 2018. The findings include: 1. Review of the laboratory's proficiency testing records for 2018 event two for miscellaneous chemistry revealed proficiency testing samples were tested once on 10.19.18 and again on 10.22.18 prior to the event cutoff date of 11.02.2018. 2. Interview with the laboratory director and the lead testing person on May 27, 2021 at 10:30am confirmed the proficiency testing samples for 2018 event two for miscellaneous chemistry were tested twice. The interviews also confirmed that patient samples are not routinely tested more than once. The laboratory failed to test proficiency testing samples the same number of times it tests patient samples for one of twelve proficiency testing events.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records for Testosterone, Thyroid Stimulating Hormone (TSH), and Prostate Specific Antigen (PSA), and interviews with the laboratory director and lead testing person, the laboratory failed to retain quality control records to include expiration dates and dates the controls were in use for patient testing in 2018, 2019, 2020, and 2021. The finding include: 1. Review of the laboratory's quality control records for Testosterone, TSH, and PSA revealed the following: No expiration date or inclusive dates of use was retained for control kit lots 1801022-5, 1801022-6R,1801022-8, 1903003-4, 1903003-7, 1903003-8, 1910046-1, and 2007010-1. 2. Interviews with the laboratory director and lead testing person on May 27, 2021 at 11:00am confirmed the laboratory failed to retain expiration dates and dates in use for multiple lots of quality control materials in 2018, 2019, 2020, and 2021.
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 (PT) records and interviews with the laboratory director and lead testing person, the laboratory failed to retain all proficiency testing records in 2018, 2019, 2020 and 2021. The findings include: 1. Review of the laboratory's proficiency testing records revealed the performance evaluation reports were not retained for the following events: Miscellaneous chemistry: 2018 event two and 2019 event two. Core Chemistry: 2019 events one, two and three, 2020 events two and three and 2021 event one. 2. Interviews with the

	laboratory director and lead testing person on May 27, 2021 at 11:00 am confirmed the laboratory failed to retain proficiency testing performance evaluations in 2018, 2019, 2020 and 2021 (seven of twelve PT events reviewed).
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control and patient test records, the laboratory's quality assessment forms, and interviews with the laboratory director and lead testing person, the laboratory's quality assessment process was ineffective when it failed to detect and correct problems with recording of quality control lot numbers and quality control ranges in 2019, 2020 and 2021. The findings include: 1. Review of the laboratory's forms used for recording quality control, the laboratory's quality control package inserts and patient test logs revealed the following: Incorrect documentation of the quality control lot number that was in use for the months of April and May 2019, August and September 2020, and February and March 2021 for the Thyroid Stimulating Hormone (TSH), Testosterone, and Prostate Specific Antigen (PSA) analytes. Incorrect quality control ranges in use for Testosterone for May 2019 as follows: Package insert range for low level=140-340 ng/dL, high range=450-1050 for reagent lot numbers 1809005 and higher. Quality control ranges in use for low level=84-280 ng/mL, high range=410-950 ng/mL. Patient number eight was performed and reported using reagent lot number 1809005-1P. 2. Review of the laboratory's quality assessment forms for 2019, 2020, and 2021 revealed no problems were identified or corrective action taken for incorrect documentation of quality control lot numbers or use of incorrect quality control ranges in May 2019. 3. Interviews with the laboratory director and the lead testing person on May 27, 2021 at 10:30 am confirmed the laboratory's quality assessment processes were not effective in identifying and correcting problems with errors in recording quality control lot numbers and quality control ranges in 2019, 2020 and 2021.
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 virtual observation of the laboratory, review of the laboratory procedure manual, calibration verification records, and interviews with the laboratory director and lead testing person, testing personnel failed to follow the procedure for calibration verification in 2019 and 2020 for three of four calibration verification events that were due. The findings include: 1. Virtual observation of the laboratory on April 26, 2021

	at 11am revealed the Qualigen Fast Pak IP instrument in use for patient testing for Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and Testosterone. 2. Review of the laboratory procedure manual revealed that "Calibration verification (verifying the reportable ranges) step 1 is performed once every 6 months." 3. Review of laboratory calibration verification records revealed the following: No calibration verification records were available for 2019, or the calibration verification due July 2020. 3. Interviews with the laboratory director and lead testing person on May 27, 2021 at 10am confirmed laboratory personnel failed to follow the laboratory procedure for calibration verification every six months in 2019 and 2020, three of four calibration verifications due.
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 review of patient test reports and interviews with the laboratory director and lead testing personnel, the final patient test report for Thyroid Stimulating Hormone (TSH) and Prostate Specific Antigen (PSA) failed to include the units of measure for six of six patient reports in 2019, 2020, and 2021. The findings include: 1. Review of final patient test reports revealed the following: TSH patient reports for patient numbers 3 (reported on 03.16.21), 6 (reported on 09.16.20), and 9 (reported on 05.01.19)--no units of measure included on the patient test reports. PSA patient reports for patient numbers 1 (reported on 03.16.21), 4 (reported on 09.16.20), and 7 (reported on 05.01.19)--no units of measure included on the patient test reports. 2. Interviews with the laboratory director and lead testing personnel on May 27, 2021 at 10:30am confirmed the final patient test reports for TSH and PSA did not include units of measure for six of six patient test reports reviewed in 2019, 2020, and 2021.
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 monthly assessment forms, the laboratory's proficiency testing (PT) records and interview with the laboratory director and lead

	testing person, the laboratory director failed to review proficiency testing reports to evaluate laboratory performance in 2018, 2019, 2020 and 2021 for nine of eleven PT events. The findings include: 1. Review of the laboratory's monthly quality assessment forms revealed the following for proficiency testing: "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." All monthly quality assessment forms for September-December 2018, January-December 2019, January-March, June-December 2020, and January-March 2021 were marked as "NA." 2. Review of the laboratory's proficiency testing records revealed the following: No evidence of laboratory director review of PT performance evaluation reports for core chemistry events 2019-1, 2019-2, 2019-3, 2020-2, 2020-3, 2021-1 and miscellaneous chemistry events 2018-2, 2019-1, and 2019.2 (nine of twelve events reviewed).