

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D1105275	<b>(X3) Date Survey Completed</b> 06/13/2024
<b>Name of Provider or Supplier</b> Inspire Health Medical Group - Dermatology	<b>Street Address, City, State</b> 2335 E Kashian Ln, Ste 410, Fresno, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of documentation, review of testing personnel competency assessment records, and interview with the office manager (OM) and Quality Assurance Officer(QAO) on June 13, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the testing personnel competency for the years 2021, 2022, and 2023. Findings include: 1. Based on the lack of the laboratory's policies and procedures and competency evaluations' records the laboratory failed to have and follow written policies and procedures for competency assessment of the testing personnel (TP) for mycology and parasitology. 2. The laboratory fail to provide documentation of training and competency assessment for the TP performing tests of moderate complexity sample processing, testing, and reporting at the laboratory for the year 2021, 2022 and 2023. 3. This deficient practice was affirmed by interview with the OM and QAO on June 6, 2024, at approximately 12:00 p.m. 4. The laboratory reported an estimated total volume of 350 test samples in mycology and parasitology annually. The report was signed and dated by the laboratory director on 06/13/2024 for which competencies of the testing personnel were not performed.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

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 the lack of laboratory written policies and procedures for potassium hydroxide (KOH) and preparations for the detection of *Sarcoptes Scabiei* (scabies) and interviews with the office manager (OM) and Quality Assurance Officer (QAO); it was determined that the laboratory failed to have available and follow written procedures for mycology and parasitology test performed in the laboratory. The findings included: 1. On the day of the survey on June 13, 2024, at approximately 11:45 a.m., the laboratory failed to provide written policies and procedures for histopathology test procedures performed in the laboratory. 2. For five (3) out of five (3) random patient test results reviewed from the KOH/scabies log, all the patients had mycology or/and parasitology test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The MO and QAO confirmed on 06/13/2024 at approximately 12:00 a.m. that the laboratory did not have written policies and procedures available for mycology and parasitology tests performed in the laboratory.

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on observation, review of the laboratory records, and interviews with the office manager and Quality Assurance Officer; it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: See D5209 and D5401.