

| | | |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D0685509 | (X3) Date Survey Completed 05/13/2025 |
| Name of Provider or Supplier Dermatologists Of Southwest Ohio | Street Address, City, State 100 W Third Avenue, Suite 250, Columbus, 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 |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D0000 | A revisit was conducted on 05/27/2025 at Dermatologists of Southwest Ohio 36D0685509 for all previous deficiencies cited on 05/13/2025. All deficiencies have been corrected and no new noncompliance was identified. The laboratory is in compliance with the Conditions of Participation at 42 CFR Part 493, Laboratory Requirements. |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 record review and an interview with the Clinical Administrator, the laboratory failed to follow written policies and procedures to assess the competency of Testing Personnel (TP) #4 for the moderately complex potassium hydroxide (KOH) testing procedures performed in the subspecialty of Mycology. This deficient practice had the potential to affect 66 out of 66 patient KOH tests performed from 08/01/2024 through 05/13/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 04/30/2025 and provided on the date of the inspection found one individual qualified and listed as a TP, hired on 08/01/2024, to perform KOH testing procedures. 2. Review of the laboratory's "Competency Assessment Policy" approved via signature and date by the Laboratory Director on 02/13/2018 and provided on the date of the inspection found the following: "...During the employment...a competency assessment will be performed: a. Initially b. 6 months c. Yearly..." 3. Review of the laboratory's competency assessment documentation, provided on the date of the inspection, failed to find competency assessment records for TP #4, per the written policy. 4. The inspector requested competency records for TP #4 from the Clinical Administrator.</p> |

An interview with the Clinical Administrator confirmed that the lab failed to perform competency assessments for TP #4, per the written policy. The interview occurred on 05/13/2025 at 2:47 PM.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Clinical Administrator, the laboratory failed to follow written policies and procedures to perform quality control (QC) each day of testing for the moderately complex potassium hydroxide (KOH) testing procedures performed in the subspecialty of Mycology for 47 out of 49 days of testing from 08/01/2024 through 05/13/2025. This deficient practice had the potential to affect 64 out of 66 patient KOH tests performed from 08/01/2024 through 05/13/2025. Findings Include: 1. Review of the laboratory's "Potassium Hydroxide (KOH) Examination of Skin, Hair or Nails," approved via signature and date by the Laboratory Director on 02/24/2025 and provided on the date of the inspection found the following: "...Each day that is procedure is performed, a second level of sample will be provided by testing each patient specimen in duplicate..." 2. Review of the laboratory's QC documentation, provided on the date of the inspection, failed to find evidence of QC performed, per the written policy. 3. The inspector requested QC records from the Clinical Administrator. An interview with the Clinical Administrator confirmed that the lab failed to perform QC for 47 out of 49 days of patient testing, per the written policy. The interview occurred on 05/13/2025 at 2:47 PM.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Clinical Administrator, the laboratory failed to follow written policies and procedures to perform quality assessment (QA) in the analytic system for the moderately complex potassium hydroxide (KOH) testing procedures performed in the subspecialty of Mycology from 08/01/2024 through 05/13/2025. This deficient practice had the potential to affect 66 out of 66 patient KOH tests performed from 08/01/2024 through 05/13/2025. Findings Include: 1. Review of the laboratory's "KOH Testing Policy and Procedure," approved via signature and date by the Laboratory Director on 02/24/2025 and provided on the date of the inspection found the following: "...A clinical staff member will do a quality assurance evaluation for at least one Scabies/KOH test per month..." 2. Review of the laboratory's QA documentation, provided on the date of the inspection, failed to find evidence of a QA evaluation performed monthly, per the written policy. 3. The inspector requested QA records for 08/01/2024 through 05/13/2025 from the Clinical Administrator. An interview with the Clinical Administrator confirmed that the lab failed to perform a QA evaluation monthly from 08/01/2024 through 05/13/2025, per the written policy. The interview occurred on 05/13/2025 at 2:24 PM.