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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D2119599 | (X3) Date Survey Completed 04/15/2021 |
| Name of Provider or Supplier St Joseph Dermatology And Vein Clinic | Street Address, City, State 2900 Niles Road, Saint Joseph, MI | |
| 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 |
|---------------------------|--|
| D3027 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #4 (TP4), the laboratory failed to retain test requisitions for at least 2 years for 2 (Patients CH1 and PJ4) of 10 patient test records reviewed. Findings include: 1. A review of patient test records revealed a lack of documentation of test requests for the following patients: a. Patient CH1 had a Potassium Hydroxide (KOH) preparation test performed on 3/16 /21. b. Patient PJ4 had a KOH preparation test performed on 2/22/21. 2. An interview on 4/15/21 at 10:23 am with TP4 confirmed the laboratory did not retain test requisitions for the patients listed above.</p> |
| D3041 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #4 (TP4), the laboratory failed to retain test reports for at least 2 years for 2 (Patients CH1 and PJ4) of 10 patient test records reviewed. Findings include: 1. A review of patient test</p> |

records revealed a lack of documentation of test reports for the following patients: a. Patient CH1 had a Potassium Hydroxide (KOH) preparation test performed on 3/16 /21. b. Patient PJ4 had a KOH preparation test performed on 2/22/21. 2. An interview on 4/15/21 at 10:23 am with TP4 confirmed the laboratory did not retain test reports for the patients listed above.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #4, the laboratory failed to evaluate for testing personnel performing Potassium Hydroxide (KOH) and Scabies preparations for 2 (April 2019 to April 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's competency records revealed a lack of a documented competency assessment for the following testing personnel in performing KOH and Scabies preparations between April 2019 to April 2021: a. Testing Personnel #1 b. Testing Personnel #2 c. Testing Personnel #3 3. An interview on 4/15 /21 at 10:05 am with TP4 confirmed the above findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #4 (TP4), the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) and Scabies preparations at least twice annually for 2 (April 2019 to April 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of two verification of accuracy testing events performed for KOH and Scabies preparations between April 2019 and April 2021. 2. An interview on 4/15/21 at 10:05 am with TP4 confirmed the laboratory did not verify the accuracy of its testing twice annually for the tests listed above.

D6122

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #4, the technical supervisor failed to include monitoring the recording and reporting of test results in staff competency assessments for 2 (Testing Personnel #4 and #5) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the

laboratory's competency assessment records revealed a lack of documentation of monitoring the recording and reporting of test results on the competency assessments for Testing Personnel #4 and #5. 2. An interview on 4/15/21 at 9:51 am with Testing Personnel #4 confirmed the Technical Supervisor did not document the monitoring of recording and reporting of test results on competency assessments.

D6126

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Testing Personnel #4, the technical supervisor failed to include the assessment of problem-solving skills in staff competency assessments for 2 (Testing Personnel #4 and #5) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency assessment records revealed a lack of documentation of the assessment of problem-solving skills on the competency assessments for Testing Personnel #4 and #5. 2. An interview on 4/15/21 at 9:51 am with Testing Personnel #4 confirmed the Technical Supervisor did not document the assessment of problem-solving skills on competency assessments.