Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0935092	01/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Gem State Dermatology	388 E Parkcenter Blvd, Boise, ID	

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 a review of proficiency testing (PT) records from Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory lead on 1/17 /2024, the laboratory failed to sign PT attestations for 2023. The findings include: 1. A review of PT records from WSLH for the two events in 2023 identified that the laboratory director and testing personnel failed to sign the attestation statements for potassium hydroxide (KOH) slide examination testing for all 2023 events. 2. An interview with the laboratory lead on 1/17/2024 at 8:29 am confirmed that the laboratory director and testing personnel failed to sign attestation statements for all KOH PT 2023 events. 3. The laboratory reports performing 1,000 KOH slide examination tests annually.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Academy of Family Physicians (AAFP) and Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory lead on 1/17/2024, the laboratory director failed to

	review PT results for 2022 and 2023. The findings include: 1. A review of PT records from AAFP for the three events in 2022 identified that the laboratory director failed to review and evaluate graded results for potassium hydroxide (KOH) slide examination testing for all 2022 events. 2. A review of PT records from WSLH for the two events in 2023 identified that the laboratory director failed to review and evaluate graded results for KOH testing for all 2023 events. 3. An interview with the laboratory lead on 1/17/2024 at 8:29 am confirmed that the laboratory director failed to review and evaluate the graded KOH PT results for all events in 2022 and 2023. 4. The laboratory reports performing 1,000 KOH slide examination tests annually. 5. This is a repeat deficiency from the 2/17/2022 survey.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a lack of documentation of verification of performance specifications for digital pathology and an interview with the laboratory lead on 1/17/2024, the laboratory failed to ensure test performance specifications were established and verified before patient testing began in October 2022. The findings include: 1. A lack of documentation for the verification of performance specifications for digital pathology identified that the laboratory failed to establish diagnostic concordance between digital images and glass slides before converting to digital pathology in October 2022. 2. A lack of documentation for the verification of performance specifications for digital pathology identified that the laboratory failed to confirm that digital images and patient information transmitted by the reference laboratory were received in their entirety and accurate. 3. An interview with the laboratory lead on 1/17 /2024 at 8:27 am confirmed the above findings. 4. The laboratory reports performing 648 dermatopathology cases annually.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of patient reports and an interview with the laboratory lead on 1/17

	/2024, the laboratory failed to have documentation of Hematoxylin and Eosin (H&E) stain quality control (QC) since October 2022. The findings include: 1. A review of patient reports identified that the laboratory failed to document QC of H&E stained slides after converting to digital pathology in October 2022. 2. An interview with the laboratory lead on 1/17/2024 at 9:08 am confirmed that the laboratory failed to have documentation of H&E stain QC since October 2022. 3. The laboratory reports performing 648 dermatopathology cases annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) documents from American Academy of Family Physicians (AAFP) and Wisconsin State Laboratory of Hygiene (WSLH), the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, laboratory policies and procedures, a lack of documentation and interviews with the laboratory lead on 1/17/2024, the laboratory director failed to ensure that digital pathology verifications were performed, that PT graded results were reviewed, that testing personnel had appropriate training and were competent to perform testing, to ensure policies and procedures were available for testing personnel to follow, that quality controls were documented for patient result reporting and that the laboratory had a quality assurance plan. See D6082, D6091, D6093, D6094, D6103 and D6106.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 a lack of documentation for the verification of performance specifications for digital pathology and an interview with the laboratory lead on 1/17/2024, the laboratory director failed to ensure test performance specifications were established and verified before beginning patient testing in October 2022. The findings include: 1. A lack of documentation for the verification of performance specifications for digital pathology identified that the laboratory failed to establish diagnostic concordance between digital images and glass slides and verify that digital images and patient information transmitted by the reference laboratory was accurate before converting to digital pathology in October 2022. See D5423 2. An interview with the laboratory lead on 1/17/2024 at 8:27 am confirmed the above findings. 3. The laboratory reports performing 648 dermatopathology cases annually.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure 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 a review of proficiency testing (PT) records from American Academy of Family Physicians (AAFP) and Wisconsin State Laboratory of Hygiene (WSLH) and an interview with the laboratory lead on 1/17/2024, the laboratory director failed to review PT results for 2022 and 2023. The findings include: 1. A review of PT records from AAFP for the three events in 2022 and records from WSLH for the two events in 2023 identified that the laboratory director failed to review and evaluate graded results for potassium hydroxide (KOH) slide examination testing for 2022 and 2023. See D5211 2. An interview with the laboratory lead on 1/17/2024 at 8:29 am confirmed the above finding. 3. The laboratory reports performing 1,000 KOH slide examination tests annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of patient reports and an interview with the laboratory lead on 1/17 /2024, the laboratory director failed to ensure documentation of Hematoxylin and Eosin (H&E) stain quality control (QC) before patient testing was reported. The findings include: 1. A review of patient reports identified that the laboratory director failed to ensure documentation QC of H&E stained slides after converting to digital pathology in October 2022. See D5473 2. An interview with the laboratory lead on 1 /17/2024 at 9:08 am confirmed the above finding. 3. The laboratory reports performing 648 dermatopathology cases annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures and an interview with the laboratory lead on 1/17/2024, the laboratory director failed to establish a quality assurance (QA) policy to ensure accurate and reliable test results. The findings include: 1. A review of the laboratory policies and procedures identified that the laboratory director failed to establish and follow a QA policy to monitor and assess general laboratory systems, preanalytic, analytic and post analytic activities that

	identifies and corrects failures in quality. 2. An interview with the laboratory lead on 1 /17/2024 at 8:50 am confirmed the above finding. 3. The laboratory reports performing 1648 tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, training and competency assessment records and an interview with the laboratory lead on 1/17/2024, the laboratory director (LD) failed to establish written policies and procedures to assess testing personnel (TP) competency. The findings include: 1. A review of laboratory procedures identified that the LD failed to establish policies or procedures to assess TP initial, semiannual and annual competency. 2. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessments for potassium hydroxide (KOH) slide examination testing for four (4) of four (4) TP in 2022 and 2023. 4. A review of training and competency assessment records identified that the laboratory failed to have initial training, six month competency assessments for KOH slide examination testing for one (1) TP in 2022. 5. An interview with the laboratory lead on 1/17/2024 at 8:22 am, confirmed the above findings. 6. The laboratory reports performing 1,000 KOH slide examination tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and an interview with the laboratory lead on 1/17/2024, the Laboratory Director (LD) failed to ensure that there were laboratory policies and procedures for all laboratory activities. The findings include: 1. A review of the laboratory procedures identified that the LD failed to ensure that procedures were available for digital pathology testing and proficiency testing for testing personnel to follow. 2. An interview with the laboratory lead on 1/17/2024 at 8:50 am confirmed that the LD failed to ensure the above policies were available. 3. The laboratory reports performing 1648 tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education

	appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory lead on 1/17/2024, the technical supervisor (TS) failed to assess employee training and competency. The findings include: 1. The CMS 209 identified four (4) testing personnel (TP) performing potassium hydroxide (KOH) slide examination testing. 2. A review of training and competency assessment records identified that the TS failed to have annual competency assessments for four (4) of four (4) TP in 2022 and 2023. 4. A review of training and competency assessment records identified that the TS failed to have initial training, and a six month competency assessment for one (1) TP in 2022. 5. An interview with the laboratory lead on 1/17/2024 at 8:22 am, confirmed the above findings. 6. The laboratory reports performing 1,000 KOH slide examination tests annually.