

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D1063322	<b>(X3) Date Survey Completed</b>  07/13/2021
<b>Name of Provider or Supplier</b>  Impactlife	<b>Street Address, City, State</b>  3420 Rider Trail South, Earth City, MO	
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>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of Sysmex XE-2100D, BacT/ALERT, BioRad Manual IH Gel System, BioRad antibody identification (ID) reagents, Quotient antibody ID panel cells in BioRad gel, BioRad Papain, COBE 2991, and IH-Incubator L verification procedures and interview with the laboratory director (LD), the laboratory director (LD) failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing. Findings: 1. Review of verification procedures for the Sysmex XE-2100D hematology analyzer and the BacT/ALERT blood culture analyzer in the processing testing lab showed no documentation that the verification procedures were adequate, reviewed and approved by the laboratory director to determine the accuracy, precision, reportable range and reference range verification. 2. Review of verification procedures for the BioRad Manual IH Gel System, BioRad antibody identification (ID) reagents, Quotient antibody ID panel cells in BioRad gel, BioRad Papain, COBE 2991, and IH-Incubator L in the reference testing lab showed no documentation that the verification procedures were adequate, reviewed and approved by the laboratory director to determine the accuracy, precision, reportable range and reference range verification. 3. Interview with the LD on July 13, 2021 at 10:00 AM confirmed the LD failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method prior to patient testing.</p>
<b>D6091</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

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 review of the 2019/2020/2021 proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in the reference lab testing site. Findings: 1. Review of PT records for the reference testing lab showed the laboratory director failed to document review of the evaluation reports obtained for all PT testing events in 2019, 2020 and to date July 13, 2021. 2. Interview with LD on July 13, 2021 at 10:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in the reference lab testing site.

**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 review of blood bank quality control (QC) and interview with the laboratory director (LD) the LD (whom is also the blood bank technical supervisor) failed to ensure blood bank quality control programs were maintained. Findings: 1. Review of blood bank QC for 2019, 2020 and to date July 13, 2021 showed no LD oversight of blood bank QC. 2. Interview with the LD on July 13, 2021 at 12:15 PM confirmed the LD failed to ensure blood bank quality control programs were maintained.

**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 lack of blood bank procedures and interview with the laboratory director (LD), the LD failed to ensure an approved blood bank procedure manual was available for 115 of 115 blood bank procedures. Findings: 1. Review of blood bank procedures showed no LD approval of blood bank procedures. 2. Interview with the LD on July 13, 2021 at 12:30 PM confirmed the LD failed to approve the blood bank procedures.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of competencies and interview with the laboratory director (LD), the technical supervisor (TS) failed to evaluate and document the performance for six of nine testing personnel in 2019, 2020 and to date July 13, 2021. Findings: 1. Review of 2019, 2020 and to date July 13, 2021 competencies showed no annual competencies documented by the TS for testing personal #2, #3, #4, #5, #6 and #7. 2. Interview with the LD on July 13, 2021 at 12:15 PM confirmed the TS failed to evaluate and document the performance annually of six testing personnel.