



PLAN OF CORRECTION WORKSHEET

This document provides the elements of the plan of correction your facility will receive in response to the findings identified in your Laboratory Evaluation Report. This document is a worksheet and is not to be submitted as your plan of correction.

If this document is submitted it will be returned.

The expectation is that all areas overseen by the laboratory and for which the laboratory is responsible have been reviewed for the same or similar nonconformity. Areas include, but are not limited to, transfusion medicine, point of care testing, patient service center, limited laboratory service, respiratory department, oncology unit, etc.

ROOT CAUSE: Provide a **summary** of the root or contributing cause(s) of the deficiency to include what happened, why and how the nonconformity occurred, when the nonconformity began and who was involved.

PATIENT IMPACT:

Please describe the impact of this nonconformity on patient results. If there was impact, describe the impact and what actions were taken to remedy the impact. If there was no impact, explain why.

CORRECTIVE ACTION:

What change(s) was put in place to ensure there will not be a repeat of this deficiency?

If applicable, what policies, procedures and processes were changed to ensure there will not be a repeat of this deficiency?

How were staff notified of the corrective actions taken?

If additional training was required, please provide the anticipated training date(s).

Please describe the impact of this nonconformity on other areas of the laboratory. If there was impact, describe the impact and what actions were taken to remedy the impact. If there was no impact, explain why.

CORRECTIVE ACTION IMPLEMENTATION DATE:	<i>The corrective action implementation date is the last date where all steps of corrective action will be performed.</i>
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MONITOR THE EFFECTIVENESS OF THE CORRECTIVE ACTION:

What quality assurance process(es) (e.g. audits, quality indicators) will be used? Include criteria for acceptability and frequency.

Describe how the laboratory director and/or owner/representative will monitor the effectiveness of the corrective action/system change(s).