# REQUEST FOR REMEDIAL ACTION FORM

**Type of Problem: (Check all that apply)**

- ☐ **General Laboratory Systems:** Includes breach of patient confidentiality, complaint investigations, communications, personnel competency, or proficiency testing performance.
- ☐ **Pre-analytic Systems**: Activities from the time the lab test was ordered through the time the sample was processed and ready to be tested, includes errors associated with transport, receipt and accessioning including data entry errors, or compromise of specimen identification or integrity.
- ☐ **Analytic Systems**: Activities involved in performing the test, verifying the test results, interpreting the findings, and recording the results. Includes methodological problems (procedure not performed correctly), technical problems (instrument is not functioning properly, error in instrument calibration, improper instrument maintenance, quality control test failures or flags) and reagent problems (expired reagents or controls used, reagents stored at wrong temperature or not brought to proper temperature before testing, or invalid control results accepted and client results reported).
- ☐ **Post-analytic Systems**: Activities related to reporting results and archiving results. Includes transcriptional errors, results reporting errors, and filing errors.

**Does the RFRA involve a manufacturer recall notice?** ☐ **YES or** ☐ **NO**

**SECTION 1: To be completed by Initiator and Laboratory Director or Designee**

***Statement of Deficiency/Potential Problem***

<table>
<tr><td colspan="3"></td></tr>
<tr><td colspan="3">Initiator (Print Name): Signature:<br><br>Date: Investigation Due Date:</td></tr>
<tr><td>QA Office Use Only</td><td>Date Received:<br><br>Assigned RFRA No.:</td><td>Laboratory Director or Designee Signature:</td></tr>
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**SECTION 2: To be completed by Investigator (and Section Supervisor, if applicable)**

***Summary of Root Cause Analysis***

| Is there evidence that this problem occurred before and actions previously implemented have failed? **Yes or No** |
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***Corrective/Preventive Action***

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| **Investigator (Print Name):** | **Signature:** |
| **Supervisor Signature:** | **Date:** |

## SECTION 3: To be completed by Laboratory Director or Designee

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|---|---|
| RFRA Completion Date: | Signature: |
| Timeframe to Monitor RFRA, as applicable: | |
| Management Review Date: | Signature: |
| Management Review Notes: | |

## SECTION 4: Review by Staff, as applicable

| Signature | Date | Signature | Date |
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