Document Owner: LPO AQ04 Complaints and Product Actions

**PART A – CUSTOMER CONTACT REPORT**

(TO BE COMPLETED FOR ALL INCIDENTS)

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| --- | --- | --- | --- | --- |
| 1. General Information | | | | |
|  | Incident # | Date of Customer Contact | Date entered into business partner/ APOC complaint system | Date closed in business partner complaint system |
| Business Partner |  |  |  |  |

|  |  |
| --- | --- |
| **Business Partner Information** | **Customer Information** |
| Name: | Name: |
| Street: | Street: |
| City: | City: |
| State : | State : |
| Post Code: | Post Code: |
| Country: | Country: |
| Contact Name: | Contact Name: |
| Phone: | Phone: |
| Fax: | Fax: |
| e-mail: | e-mail: |

Check this box if no customer contacts were received this month.

Indicate Month **,**  Year of this report

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **2. Product Information** | | | | | | | |
| Product Name: | | Part or List Number: | | | | Lot or Serial Number: | |
| Product Name #2: | | Part or List Number #2: | | | | Lot or Serial Number #2: | |
| Analyzer Software Version: | | CLEW version: | | | | Central Data Station Version: | |
| Language: | | Unit Set: | | | |  | |
| **3. Incident Description (see Q04.01.007 for requirements)**  A clear concise problem statement describing the customer contact must be documented as part of the initial text information recorded in the complaint file. Subsequent information must be documented in the complaint file when received. At times, the TSS may request the business partner to perform several different troubleshooting steps to aid in the identification of the cause of the reported issue. | | | | | | | |
|  | | | | | | | |
| **4. Documentation of Investigation Conducted by Business Partner**  Note: Associated documents used to provide guidance, troubleshoot or resolve the customer issue/concern, must be referenced. | | | | | | | |
|  | | | | | | | |
|  | | | **Yes** | | **No** | **Comments** | |
| **Incident review** | | |  | | | | |
| Is this an Adverse Event (per Q04.01.007 Customer Contact Reporting Requirements for Business Partners)?  ***Adverse Event*** *-* **Any incident where the use of the product is suspected to have resulted in or been associated with an adverse outcome (death or serious injury) to a patient or user of the product.**  **Adverse Event Evaluation Questions**   1. **Was quality control or other validity testing performed on the i-STAT System considered unacceptable?**      1. **Were suspect (unexpected) results generated by the i-STAT System?** 2. **Were these suspect (unexpected) results released to a physician or care giver?** 3. **Did the suspect test results or delay in reporting results impact patient management? If yes describe** 4. **Did the result necessitate medical or surgical intervention? If yes describe**   If the answer to any of the questions above is yes – submit form to APOC Technical Support ([oustechsvc@apoc.abbott.com](mailto:oustechsvc@apoc.abbott.com)) within **24 hours**. | | |  | |  |  | |
| Did the product malfunction?  **Malfunction:** ***The failure of a device to meet its performance specifications or otherwise perform as intended (for example an abnormal rate of suppressed results). Performance specifications include all claims made in the labeling for the device.***  If yes, describe in the comments section and submit form to APOC Technical Support ([oustechsvc@apoc.abbott.com](mailto:oustechsvc@apoc.abbott.com)) within **24 hours.** | | |  | |  |  | |
| **Incident Report** | | |  | |  |  | |
| Was the incident/adverse event/malfunction reported to a local regulatory agency?  If yes, provide copies of any communication documentation e.g., forms. | | |  | |  |  | |
| **5. Documentation of Resolution Conducted By Business Partner** | | | | | | | |
|  | | | | | | | |
| **6. Product return Information** | | | | | | | |
| RGA number: | Item | | | Serial Number or Lot No. | | | Quantity |
| Chargeable PO Number: | | | | | | | |