**Complaints: Recording, Preliminary Evaluation and Referral for LC-MSMS Laboratory Developed Tests (LDT,) Standard Operating Procedure (SOP) Template**

*MSACL-CAC disclaimer: The information provided in this guidance document template is for general informational purposes only and should not be considered legal advice. Regulatory rules and compliance requirements can vary significantly depending on specific circumstances.  It is essential to consult with a qualified attorney or regulatory professional who is familiar with your specific circumstances and can provide guidance tailored to your situation before taking any actions based on the content presented herein.*

**Guide to significance of background/text colors:**

***MSACL disclaimer***

**Text copied from Code of Federal Regulations (CFR)**

**Procedural text, addresses a CFR citation directly, no interpretation by CAC Template author(s)**

**Procedural text, a CFR citation interpreted by CAC Template Author(s), no specific CFR language**

***Code of Federal Regulations 820.198. Complaint Files***

*(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:*

*(1) All complaints are processed in a uniform and timely manner;*

*(2) Oral complaints are documented upon receipt; and*

*(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under*[*part 803 of this chapter*](https://www.ecfr.gov/current/title-21/part-803)*, Medical Device Reporting.*

*(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.*

*(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.*

*(d) Any complaint that represents an event which must be reported to FDA under*[*part 803 of this chapter*](https://www.ecfr.gov/current/title-21/part-803)*shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by*[*§ 820.198(e)*](https://www.ecfr.gov/current/title-21/section-820.198#p-820.198(e))*, records of investigation under this paragraph shall include a determination of:*

*(1) Whether the device failed to meet specifications;*

*(2) Whether the device was being used for treatment or diagnosis; and*

*(3) The relationship, if any, of the device to the reported incident or adverse event.*

*(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in*[*paragraph (a)*](https://www.ecfr.gov/current/title-21/section-820.198#p-820.198(a))*of this section. The record of investigation shall include:*

*(1) The name of the device;*

*(2) The date the complaint was received;*

*(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;*

*(4) The name, address, and phone number of the complainant;*

*(5) The nature and details of the complaint;*

*(6) The dates and results of the investigation;*

*(7) Any corrective action taken; and*

*(8) Any reply to the complainant.*

*(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.*

*(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:*

*(1) A location in the United States where the manufacturer's records are regularly kept; or*

*(2) The location of the initial distributor.*

**I. PURPOSE (CFR 820.198[a,b,c,d,e])**

This procedure describes how Complaints received about an LC-MSMS LDT performed by this laboratory are received, recorded, tracked, referred to the LDT Complaints and Nonconforming Events Quality Assurance (LDT-QA) Committee and how related documents are stored. Also described is the preliminary evaluation performed within 24 hrs of receiving a Complaint or Nonconforming Event report (CNCE) to determine if death or serious injury to a patient may be related to an LC-MSMS LDT result. See also the LDT-QA Committee Actions and Mandatory Reporting SOP. In this procedure, the term Nonconforming “Event” is interchangeable with Nonconforming “Product”.

See section III. Definitions, for lists of the LC-MSMS LDT performed by this laboratory and the definition and responsibilities of the LDT-QA Committee (CFR 820.198[a,b]).

**Figure 1. Diagram of Complaints, Nonconforming Events Relationship to Corrective Action/Reporting**



**II. SCOPE (CFR 820.198[a,b,c,d,e])**

This SOP and attached forms apply to all LC-MSMS LDT and all laboratory personnel.

A Complaint may be received from a patient, patient’s health care proxy, patient’s relative or friend, clinician (physician, physician assistant, nurse-practitioner, etc.), nurse, pharmacist, any other health care provider, or the medical examiner’s office in any of the formats listed below. If uncertain about the source or nature of the Complaint, always record and refer any Complaint, as appropriate for your role, by following this SOP. Never ignore a possible Complaint.

**Incomplete Complaints.** See section IV.2 below on how to handle an incomplete Complaint (i.e. insufficient information is provided to complete a Complaint Recording Form).

**Labeling or Test Information Complaints.** See IV.4 below, Receiving and Referral of Complaints, for how to handle a Complaint received about LC-MSMS LDT *information* provided by the laboratory *instead of* a Complaint about a *specific LDT result*. Test information may be shown online in a laboratory information system (e.g. LIS name such as SCC Soft Computer, Clinisys [Sunquest], Meditech); or in a separate online test information catalog (e.g. ARUP Laboratories Test Directory), or within an electronic medical record application (e.g. EMR name such as Epic Systems) or within a patient portal lookup application (e.g. name such as MyChart). Test information is presented online for use before ordering; AND at the time a test is ordered; AND when test results are viewed by clinicians or in a different application by patients (21 CFR 820.198[c]). Test information should not, but may, differ between software applications. Therefore, it is important to identify specifically, if possible, which software application is the source of the Complaint.

Complaints may be received as: (CFR 820.198[a])

**II.1** An email to any laboratory personnel through the EMR email, LIS email or stand-alone email provider (e.g. MS Outlook),

**II.2** A text message to any laboratory personnel on a personal or laboratory telephone,

**II.3** A hard copy letter or note, addressed to any laboratory personnel or to the department,

**II.4** A telephone call or voice mail to the laboratory section performing the LC-MSMS LDT,

**II.5** A telephone call or voice mail to any other laboratory section, including administrative offices,

**II.6** An in-person verbal message to any laboratory personnel.

**III. DEFINITIONS**

**III.1 List of LC-MSMS LDT performed by this laboratory:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Date LDT in use for Patient Care** | **LC-MSMS LDT Name Displayed in EMR (e.g.Epic)** | **LIS mnemonic(s) & FDA LDT Product Code** | **LC-MSMS LDT Method SOP name** |
| 1. | 7/4/14 | Opiates Confirmation, Urine | OPCFM & SCE | Urine Opiates Confirmation by LC-MSMS |
| 2. | 9/07/24 | Testosterone, Female  | TSTOMS & SCF | Testosterone by LC-MSMS |
|  |  |  |  |  |

**III.2 LDT-QA Committee for Review, Action, and Reporting on LC-MSMS LDT Complaints and Nonconforming Events (CNCE) (CFR 820.198 [a,b,c,d])**

The LDT-QA committee is the formally designated unit that has responsibility to review, evaluate, investigate as necessary, require corrections and preventative action, removal, internal reporting, and Medical Device Reporting (MDR) to the FDA as needed for CNCE that may be related to failure of an LC-MSMS LDT result(s) (CFR Part 803, 820.198[b]). The LDT-QA committee has scheduled meetings (define interval – weekly, monthly). If preliminary evaluation suggests that death or serious injury to a patient may be related to an LC-MSMS LDT result failure, the committee will meet ad hoc within 48 hrs of receiving the CNCE referral. See section III.5 below for the FDA definition of serious injury to a patient. For a complete description of the LDT-QA Committee responsibilities see the LDT-QA Committee, Actions and Medical Device Reporting SOP. Review and investigations of CNCE must be conducted by the LDT-QA Committee in a timely and uniform manner. Current committee members are:

**III.2.1** The LC-MSMS LDT section supervisor, name & job title (indicate if Committee Chair)

**III.2.2** The LC-MSMS LDT section Director/designate, name & job title (indicate if Committee Chair)

**III.2.3** The laboratory QA Director/designate, name & job title. This committee member cannot work in the LC-MSMS laboratory section OR report to the LC-MSMS supervisor or Director.

**III.2.4** If applicable, the individual responsible for LC-MSMS test method development and validation, name & job title.

**III.3 Unique Device Identifier (UDI) and FDA Product Codes for LDTs (CFR 820.198 d,3)**

A UDI is the unambiguous, number identification of an LC-MSMS LDT required for reporting test problems to the FDA (see SOP for Medical Device [MDR], Corrections and Removals Reporting). UDIs are assigned by an FDA-accredited issuing agency. Product codes are the FDA’s method of classifying and tracking medical devices. They are assigned and maintained by the FDA.

FDA **Product Codes for LDTs** (partial listing) are:

1. **SCE** - IVD offered as LDT, first marketed before May 6, 2024, not modified beyond scope described in preamble to LDT Final Rule

2. **SCF** - LDT, unmet need within an integrated healthcare system

3. **SCG** - Modified version of another manufacturer’s FDA-authorized test within scope described in preamble to LDT Final Rule

4. **SCH -** LDT, approved by NYS CLEP

5. **SCJ** - LDT, NOT under a targeted enforcement discretion policy (see preamble to LDT Final Rule)

Consult the MDR SOP, individual method SOPs, and/or the LC-MSMS supervisor/designate to verify the correct UDI and Product Code for an LDT associated with a Complaint or NCE.

 **III.4 LC-MSMS LDT Complaint Log File (CFR 820.198[e])**

A hard copy or online table/database of all LC-MSMS LDT related Complaints received by the laboratory is maintained as the Complaint Log file. The default sorting of Complaints in the Log is by date/time of receipt, entered as the Complaint UI (see attached Log File MS Excel Template). See IV.2.1 below for a description of the Complaint UI. The hard copy file location or online file path or link to the LDT Complaints log is \_\_\_\_\_\_\_\_\_\_. *Disclaimer to template users: For Complaint tracking, use of an ACCESS database at a minimum, or the better option of using a healthcare quality management system (QMS) application such as MediaLab, is highly recommended. Tracking with MS Excel is easy and cheap but has unacceptably high risk for compromise of record integrity through user error. Tracking with a hard copy system is labor intensive and error prone for assessing trends, frequency of recurring CNCE.*

A running tally of recurring LDTs and recurring patient last names can be maintained in an Excel version of the Log by adding new LDT names and new Patient Last Names as they occur, with matching COUNTIF function statements in the “LDT Tally” and “Patient Tally for this Last Name” fields. Existing COUNTIF functions should be reviewed at (add review interval) to verify/update the accuracy of the cell range.

COUNTIF statements are entered as: =COUNTIF(cell range, “text of LDT name” or “Patient Last Name”).

**III.5 Serious injury as defined by the FDA is:**

**III.5.1** Life threatening; or,

**IIII.5.2** Results in permanent impairment or damage to a body function or structure; or,

**III.5.3** Requires medical or surgical intervention to preclude permanent impairment or damage to a body function or structure.

**III.6 Definition of the Batch Cover Sheet**

A batch cover sheet provides traceability of components used in each patient reportable LC-MSMS batch of specimens, by recording lot/serial numbers of blanks, calibrators, QC, instrument(s) used, batch related file names, analysts, reagents, other consumables, and provides a checklist/reminders/ for LC-MSMS data review and parameter recording [e.g. heat block temperature] (see attached MSACL-CAC\_ Batch Cover Sheet template).

**IV. PROCEDURE**

**Receiving, Recording, Logging, Preliminary Evaluation, Referral and Document Storage for Complaints** (CFR 820.198 [a,b,c,d,e] – see also Summary Table 1, below)

The LC-MSMS LDT Complaint Reporting form should be completed and reported to the LC-MSMS or QA supervisor within the same shift (< 8 hrs) of receiving a Complaint. (see attached Complaint Recording form template).

**IV. 1 Receiving a Complaint** (CFR 820.198[a]):

**IV.1.1 In-person or telephone call**

* 1. If received by the section performing the test – begin the Complaint Recording process described in IV.2 below. Only personnel with documented, current competency for Complaint recording should enter data in the Complaint form. If unable to record the Complaint in real time, at a minimum, record the date/time the Complaint was received, the name and contact information for the Complainant and inform the LC-MSMS supervisor/designate within the same shift (< 8 hrs).
	2. If received by another section and the LC-MSMS LDT section is staffed – note the date/time and ask the Complainant if you can transfer the call, OR provide directions to the LC-MSMS LDT section, OR escort the Complainant to the LC-MSMS LDT section if the Complainant agrees. Supply the date/time the Complaint was received to LC-MSMS staff.
	3. If the Complainant refuses to be transferred OR the laboratory section performing the LDT is not staffed:
	4. If you have been trained and are current in competency testing for LC-MSMS LDT Complaint processing – record and report the Complaint, see IV.2 below.
	5. If you are NOT current in competency testing for LC-MSMS LDT Complaint processing – refer the problem verbally to the Chair or a member of the LDT-QA committee within the same shift (< 8 hrs) (see also IV.1.2.B below). At a minimum, record the date/time the Complaint was received and the name and contact information for the Complainant.

**IV.1.2 E-mail or Text message**

1. If received by laboratory personnel in the section performing the LC-MSMS LDT – begin the Complaint Recording process described in IV.2 below. Only personnel with documented, current competency for Complaint recording should enter data in the Complaint form.

B. If received by another section, forward the email/text to the LC-MSMS or QA supervisor/desig-

nate with a request to confirm receipt. If a receipt confirmation is not received within the expected time frame (supply appropriate timeframe, 24 hrs recommended) – escalate the problem to the Chair or a member of the LDT-QA committee (see III.2 above).

**IV.2 Recording a Complaint (**CFR 820.198 [b,c,d,e])

Only personnel with documented, current competency for Complaint recording should enter data in the Complaint form.

**Incomplete Complaint Information**

If a verbal Complainant declines or is unable to provide or a written Complaint has insufficient information to identify the patient, specimen, LDT, problem with the result cited in the Complaint; at a minimum record the date/time the Complaint was received, the Complainant name and contact information. Consult the QA or LC-MSMS section supervisors/designates within the same shift (<8 hrs) about next steps for handling an incomplete Complaint. If you use email/text/voice mail to consult a supervisor, request a receipt confirmation. If the receipt confirmation is not received within (supply timeframe, 24 hrs recommended) – escalate the Complaint to the Chair or a member of the LDT-QA committee.

**Handling Complaints About Laboratory Test Information Only (Labeling but No Test Result cited-21 CFR 820.198[c])**

Record any Complaint about *information (labeling)* provided by the laboratory related to LC-MSMS LDT, as well as Complaints about *a specific test result*. Use the same LC-MSMS LDT Complaint Recording Form (e.g. TAT stated is wrong, days listed for test performance are wrong, other inaccurate, incomplete, or confusing information) from any laboratory source [laboratory test catalog, any function within the EMR or LIS, patient portal for results lookup]). For fields in the form that ask for specimen/patient specific information (e.g. 4. patient name; 6. MR#; 11. specimen date/time; 13. Sample UDI – enter NONE if not applicable or not provided). For field 7. Complainant relationship to patient – enter the role the Complainant states for themselves when reporting a Complaint about test information (i.e. “a provider”, “a patient”, “a nurse”, etc.). If a patient is the Complainant – acceptable entries for Complaint Form field #4 Patient Name and in the Complaint Log field “Patient Last Name” are “NONE” or “see #3 (on the form)” or re-enter the patient name/last name (same as #3 Complainant Name on the form).

Test information should not, but may, differ between software applications that can be viewed by providers or patients to obtain LC-MSMS LDT related information. Therefore, it is important to identify, if possible, the exact software application that is the source of the Complaint.

**Filling in the Complaint form (CFR 820.198 [a,b,c,d,e])**

**IV.2.1 Enter the Complaint Unique Identifier (UI)**, defined as the year, month day, hour, minute (24 hr clock) the complaint was received, written as YYMMDD-HHMM. See also IV.2.2. Add a sequence number if necessary - -01, -02, etc. An example is 250506-1200 for May 6, 2025 at 12 noon.

**IV.2.2**  **Enter Complaint date/time,** which is defined by the FDA as the time the first person in the laboratory is made aware of the Complaint, even if that person is not associated with the LC-MSMS laboratory or QA sections and/or does not complete the Complaint Report Form. This date/time should be the same as used in the Complaint UI.

**IV.2.3 Complainant ID.** Enter the Complainant first and last name. For medical personnel Complainants enter professional title (MD, RN, PA, NP, DO, etc), and medical role (attending, intern, R1, R2, etc. resident, nurse manager, etc.), specialty/department/office/hospital unit if possible.

**IV.2.4 Patient Name. E**nter first and last name of the patient cited in the Complaint.

**IV.2.5 Complainant Contact Information.** Enter telephone number (hospital/clinic office optimal), Health System email address if available, and office/clinic street address (hospital address acceptable). Enter home contact information or hospital unit information for patient/patient proxy Complainants. Recording the Complainant’s street address is an FDA requirement.

**IV.2.6 Patient MR #.** Enter patient medical record number. Best practice, if feasible, is to look up the patient’s record in the LIS to confirm the MR# is correct before proceeding with the remainder of the form.

**IV.2.7 Complainant Relationship to Patient.** Check a box or enter relationship of the Complainant to the patient.

**IV.2.8 LDT Name.** Enter the name of the LDT cited by the Complainant. If feasible, before proceeding, look up the patient’s samples in the LIS for the cited sample date (see IV.2.11) to confirm/correct the LDT name provided by the Complainant.

**IV.2.9 What is the Complaint.** Check one of the boxes in this field if applicable. Check Other if appropriate. Add details of the Complaint.

**IV.2.10 Harm to Patient.** If not provided, ask if there was harm to the patient associated with the Complaint. Check a box as applicable. Add details of any reported harm.

**IV.2.11 Sample Collection Date/Time/Acc#.** Enter the collection date(s)/time(s) and LIS accession number(s) of the sample(s) cited in the Complaint.

**IV.2.12 Other Patients/Providers.** If the Complainant states that other patients or providers also have problems with the same LDT – check YES. If no statement is made about other patients/providers – check NO or UNKNOWN, no need to query the Complainant.

**IV.2.13 Unique Device Identifier (UDI).** Enter the LC-MSMS LDT UDI. If necessary, verify the correct UDI from the method SOP or LC-MSMS supervisor/designate.

**IV.2.14 Notifying LC-MSMS/QA Supervisor of Recorded Complaint**

Indicate the time/date that you notified the LC-MSMS or QA supervisor/designate of the Complaint. Enter the name of the supervisor’s designate if needed, and check the means of notification (email, in person, etc.). Notification should occur within the same shift (<8 hrs) of receiving the Complaint.

**IV.2.15 Complaint format.** Check the box or write in to indicate how (in what format) the Complaint was received (call, email, in person, etc.).

**IV.2.16 Reply to Complainant.** For simple matters that can be resolved within the same conversation as the first report of the Complaint (reported to wrong provider, wrong test ordered by provider, complaint is incorrectly described as a delayed result due to misunderstanding of stated TAT, etc.) – record the date, time, and summary of your reply, your name and to whom you replied. Refer all other replies to the LC-MSMS supervisor/designate, inform the Complainant that investigation is needed and that a supervisor or director will provide an initial reply within 24 hrs.

**IV.2.17 Complaint Referral.** Check the box indicating to whom you referred the Complaint. The default is to the LC-MSMS supervisor/designate within the same shift (<8 hrs). Leave the “Patient severe injury/death fields blank. See also IV.2.18 below.

**IV.2.18. Recorder and Supervisor Signature (reverse side of form).** The person filling in the Complaint form signs at “Form started by \_\_\_\_\_. The recorder does not complete the Date/Time field on this line.

The supervisor/designate receiving notification of the Complaint signs here, entering the signature date/time after performing the preliminary evaluation, and checks the “Severe Injury/Death Yes, No, Unknown” box on the Complaint form in field 17. A preliminary evaluation should occur within the same shift (<8 hrs) that the Complaint was received (see IV.3 below for details on the preliminary evaluation) (CFR 820.198[b,c,d]).

**IV.2.19 Entered in Log (reverse side of form).** Enter the Complaint in the hard copy/online Complaint Log file and sign the Complaint form with date/time of Log entry. The Log file location and instructions are shown in IV.3 below. See attached Log File form template.

**IV.3 Completing the Complaint Log** (CFR 820.198[e])

The Complaint Log hard copy location/file path/link is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Enter the Complaint UI, the LDT cited in the Complaint, and the last name of the patient cited in the Complaint.

See section III.4 above, definition of the LC-MSMS LDT Complaint Log File, on use of COUNTIF function statements in Excel to maintain a running count of recurring LDT and Patient Last name entries in the log.

**IV.4 Supervisor/designate Preliminary Evaluation and Referral of Complaints** (CFR 820.198[b,c,d])

The LC-MSMS supervisor/designate performs a preliminary evaluation of all Complaints within 24 hrs of receipt. Preliminary evaluation includes review of the Complaint form for accuracy/completeness and assessment for serious injury/death of a patient that may be related to an LC-MSMS LDT result (see IV.2.10 above).

**See III.5 for the definition by the FDA of Serious injury.** If serious injury/death of a patient related to an LC-MSMS LDT result is cited by the Complainant or seems possible after preliminary evaluation, the supervisor checks the Severe Injury/Death “Yes” box on the Complaint form (field 17) and refers the Complaint within 24 hrs of receipt to the LC-MSMS laboratory director and members of the LDT-QA committee.

The supervisor/designate preliminary evaluation may include obtaining additional information as needed, such as further communication with the Complainant, review of the LC-MSMS batch cover sheet, batch calibration and QC, QC history, batch extracted ion chromatograms and metadata (e.g. ion ratios), instrument maintenance and service records, LC-MSMS longitudinal tracking metrics (e.g. internal standard peak areas), patient clinical status from the EMR related to any stated harm, and:

**IV.4.5** After making the preliminary evaluation the supervisor/designate signs the Complaint form at line 18 and enters their signature date/time. If no serious injury/death of a patient related to an LC-MSMS LDT result is cited or suspected, the supervisor refers the Complaint in a routine manner to the LDT-QA committee for review at the next scheduled meeting.

**IV.4.6** See the LDT-QA Committee Actions and Medical Device Reporting SOP for next steps following the preliminary evaluation and referral of the Complaint (CFR 820.198[b,c,d]).

**IV.5 Storage (filing) of Complaint Files** (CFR 820.198[e])

All Complaint form fields, including signatures and the Sample UDI, should be completed before filing a hard copy in a secure location/saving an online form to the correct file path/saving the database record. Forms are filed by the LC-MSMS supervisor or designate after preliminary evaluation and if necessary referral to the LDT-QA committee within 24 hrs. There are four separate, clearly designated file folders/file drawers/online locations for these four different types of Complaint forms:

**IV.5.1** Review Pending

**IV.5.2** Reviewed, No Investigation Necessary, with LDT-QA Committee rationale and signatures

**IV.5.3** Reviewed, Investigated or Investigation in Progress, with LDT-QA Committee report

**IV.5.4** Reviewed, Medical Device Reporting to FDA, with LDT-QA Committee report, MDR e-report (separate filing is an FDA requirement)

**Table 1. Summary of Complaints Documentation and Tracking** (CFR 820.198 [a,b,c,d,e])

|  |  |  |  |
| --- | --- | --- | --- |
| **Step (# of Form field)**  | **Who does it** | **Time Limits** | **Action**  |
| 1. Note date/time Complaint received (2) | First responder | On receipt | Enter on Complaint form or refer and supply received date/time to trained staff who complete the form.  |
| 2. Assign complaint UI (1) | Trained staff | Same shift (< 8 hrs) | Use YYMMDD-MMHH that Complaint was received. |
| 3. Complete complaint form (3-19) | Trained staff | Same shift (< 8 hrs) | See also # 5-8 in table below. |
| 4. Enter complaint in the complaint log | Trained staff | Same shift (< 8 hrs) | Update Complaint UI with index number if needed, i.e.YYMMDD-MMHH\_01 or 02, etc. |
| 5. Inform LC-MSMS Sup./Designate (17) | Person starting form | Same shift (< 8 hrs) | Report to Sup./designate within same shift (< 8 hrs) even if form is incomplete. |
| **Step (# of Form field)** | **Who does it** | **Time Limits** | **Action** |
| 6. LC-MSMS Sup.-pre-lim. evaluation (17,18) | LC-MSMS Sup./designate | Within 24 hrs | LC-MSMS Sup./designate does prelim. eval., including checks for severe injury/death related to an LC-MSMS LDT result & Yes/No/Unk box on form |
| 7. Severe injury/ Death referral (17) | LC-MSMS Sup./designate | Within 24 hrs | LC-MSMS Sup. Reports/refers Complaint to LC-MSMS/QA Director & LDT-QA committee if severe injury/death & review in < 48 hrs may have occurred |
| 8. UDI  | Trained staff  | Same shift (< 8 hrs) | See method SOP. |
| 9. Initial Reply to Complainant (16)  | Trained staff or Sup/designate | Within 24 hrs | As appropriate for what is known without additional investigation, consult with LC-MSMS Laboratory Supervisor/Director if necessary. |
| 9. LDT-QA committee reviews Complaint, reply to Complainant | LDT-QA committee | Scheduled or < 48 hrs | LDT-QA committee reviews Complaint within 48 hrs if severe/injury death related to an LDT is suspected and replies to Complainant, otherwise as scheduled |
| 10. LDT-QA committee: investigation decision | LDT-QA committee | At initial review | LDT-QA committee decides to investigate or not, decision rationale & committee chair signature required on LDT-QA Committee report for this UI. |
| 11. Investigation of complaint (see #10) | LDT-QA committee | ASAP | See LDT-QA Committee Actions and Mandatory Reporting SOP template. |
| 12. Medical Device Reporting (MDR) to FDA | QA Director/ designate | 5-30 days | See MDR SOP, 30 days from Complaint receipt or 5 days if remedial action is needed to prevent a risk of substantial harm to the public health  |
| 13. Corrections/ Preventative action?  | LDT-QA committee | Event dependent | LDT-QA committee reviews investigation, sets deadline for Corrections as necessary to prevent a risk of substantial harm to the public health |
| 14. If Correction(s) -- Report to FDA  | QA Director/ designate | 5-30 days | See Corrections Reporting SOP, 30 days from Complaint receipt or 5 days if remedial action is needed to prevent a risk of substantial harm to the public health  |
| 15. Test “Removal” = pause/stop of testing with LDT if needed | LC-MSMS Lab Director | Event dependent | LC-MSMS Lab Director, as needed through consultation with LDT-QA Committee, sets time frame to prevent a risk of substantial harm to the public health |
| 16. If “Removal” – Report to FDA | QA Director/ designate | 5-30 days | See Removal Reporting SOP template, 30 days from Complaint receipt or 5 days if remedial action is needed to prevent a risk of substantial harm to the public health  |

**V. RESPONSIBILITY**

All laboratory personnel, in all sections, are responsible for correct referral within 24 hrs of LC-MSMS LDT Complaints to the LC-MSMS laboratory section. Email or verbal confirmation of a Complaint referral by LC-MSMS section personnel is required within 24 hrs of referral (see section IV.1 above).

All personnel with current competency for filling in LC-MSMS LDT Complaint forms are responsible (see Section IV.2 above) for :

A. completing the form as Complaints are received, with some exceptions

B. entering the form in the Complaint Log file,

C. notifying the LC-MSMS supervisor/designate of the Complaint within the same shift (<8 hrs) after Complaint receipt.

The LC-MSMS supervisor/designate is responsible for preliminary evaluation of all Complaints within 24 hrs. If serious injury/death of a patient appears to be associated with an LC-MSMS LDT result, the supervisor/designate is responsible for referring the event within 24 hrs of Complaint receipt to the LC-MSMS laboratory director and the LDT-QA Committee. The supervisor/designate is responsible for filing/delegation of filing for Complaint forms after preliminary evaluation.

The LDT-QA Committee reviews Complaints that may be associated with serious injury or death of a patient within 48 hrs. Other Complaints are reviewed at scheduled meetings. If Corrections and revalidation, or Removal, is needed those actions should take place/begin within 24 hrs to 5 days after committee review/investigation, depending on the risk of substantial harm to the public health.

See the LDT-QA Committee Actions and Mandatory Reporting SOP for next steps after referral of a Complaint.

**VI. EXCEPTIONS**

There are no exceptions.

**VII. SUPPLIES**

LC-MSMS LDT Complaint form

LC-MSMS LDT Complaint log

**VIII. REFERENCES**

1. FDA printable slides for Complaint Files. Accessed 09/03/2024. <https://www.fda.gov/files/about%20fda/published/Complaint-Files---Printable-Slides.pdf>

2. FDA printable slides for Nonconforming Product. Accessed 9/23/2024.

<https://www.fda.gov/files/about%20fda/published/Nonconforming-Product---Printable-Slides.pdf>

3. CLSI. Quality System Regulation for Laboratory-Developed Tests: A Practical Guide for the Laboratory. CLSI document QSRLDT. Clinical and Laboratory Standards Institute, 2024.

*MSACL-CAC disclaimer: The information provided in this guidance document template is for general informational purposes only and should not be considered legal advice. Regulatory rules and compliance requirements can vary significantly depending on specific circumstances.  It is essential to consult with a qualified attorney or regulatory professional who is familiar with your specific circumstances and can provide guidance tailored to your situation before taking any actions based on the content presented herein.*