**MSACL-CAC\_LC-MSMS LDT Complaint Recording Form\_template 1. COMPLAINT UNIQUE ID (UID = YYMMDD\_HHMM) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- |
| ***2. Date/Time of Complain****t* | **3*. Complainant first, last name,******title, medical specialty/Dept.*** |  |
| 4. **Patient first, last name** | **5. *Complainant telephone number(s), email, street address*** |  |
| **6. Patient MR #, other identifier** | **7. Complainant relationship to Patient** ☐ Provider ☐ Self (Patient) ☐ Nurse ☐ Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **8. LC-MSMS LDT in Complaint (EMR, LIS names, mnemonics or see list on reverse**) |  **9.** **What is the Complaint?** ☐ Delay in reporting  ☐ Wrong test ☐ Reported to wrong provider  ☐ Critical result not called ☐ Result is inconsistent with  a) previous results b) other, different test results c) clinical  condition (indicate a, b, or c if appropriate).  ☐ Other, add all available narrative below |  10. **Harm to patient?** ☐ Unknown ☐ No ☐ Yes – delay in diagnosis ☐ Yes – delay in treatment ☐ Yes– unnecessary treatment ☐ Yes- delay in discharge home or to other  step down unit\_\_\_\_\_\_\_\_\_\_\_ ☐ Other harm, add all available narrative |
| **11. Collection Time/Date/Acc # of Complaint sample(s)** |
| **12. Other patient(s) or providers same Complaint for this LDT?** ☐ YES ☐ NO or UNKNOWN  |
| **13. LC-MSMS LDT Unique Device Identifier (UDI)**  |
| **14. Report** same shift to . or designate using ☐ email ☐ text ☐ In Person ☐ Voice Mail (Time/Date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Designate\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **15. Complaint format** ☐ Telephone call☐ email ☐ text ☐ In person ☐ EMR/LIS email. ☐ letter |
| **16. Initial Reply to Complainant** Date\_\_\_\_\_\_\_\_\_\_\_\_ Time \_\_\_\_\_\_\_\_\_\_ Reply by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Spoke with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Summary of reply\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **17. Complaint Referral**☐ LC-MSMS Lab Supervisor☐ LC-MSMS Lab Director ☐ LDT-QA Committee☐ Department QA Committee |

**18. Form started by** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Supervisor evaluation** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date\_\_\_\_\_\_\_\_\_\_\_\_ Time\_**\_\_\_\_\_\_

**19. Entered in Log**/Database by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date\_\_\_\_\_\_\_\_\_\_\_\_\_ Time**\_\_\_\_\_\_\_\_\_ ***Mandatory Fields (2, 3, 5)***

***If referred to the LDT-QA Committee – see also “Report of CNCE Investigation”*** for this UI ***for actions, investigation, reporting about this Complaint (UI) by the LDT-QA Committee.***

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.*

Definitions:

1. A Complaint Unique Identifier (UI) is the date and time the Complaint was first received by any laboratory personnel, listed as YYMMDD-HHMM.

List of LDTs

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **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 |
|  |  |  |  |  |