

MOLECULAR DIAGNOSTICS UNIT
QUALITY SYSTEM PROTOCOL

TITLE: Handling of client complaints and User Surveys

SOP NO. MDU 0009 version 5

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ISSUED TO

COPY NO. Master

SUMMARY

This SOP details the procedure for handling complaints from clients of the diagnostic services provided by MDU.

SAFETY

There are no safety issues associated with this SOP.

1.0 CROSS REFERENCE

None

2.0 HANDLING OF CLIENT COMPLAINTS

- 2.1 Complaints may lead to logging of a NCQI, and a discussion with the leadership team. All complaints should be handled courteously and as quickly as is possible to give a satisfactory response, an appropriate timeline should be agreed by the Head of Unit and Quality Manager in addressing the NCQI. A maximum of three months should be allowed to close out the finding, however this may be extended if the issue can not be resolved due to its severity, as agreed by the Head of Department.
- 2.2 If the complaint is made by letter, fax or email copies should be made and attached, together with the original, to the complaints record sheet (**MDU-RS07**). If the complaint is by telephone, written notes should be transcribed immediately to the record sheet.
- 2.3 The Head of the Unit and Quality Manager must be made aware of any complaint as soon as possible.
- 2.4 Any records relating to the complaint (workbooks, record sheets) should be copied and attached to the complaint record sheet.
- 2.5 Risk and clinical impact on patients will be assessed by an appropriately qualified member of MDU staff who has a full understanding of the risk and clinical impact.
- 2.6 The Quality Manager, or an appropriately qualified member of MDU staff, if applicable, will conduct an investigation into the complaint, taking evidence from any member of staff who may be involved.
- 2.7 When all necessary facts have been collated The Head of the Unit, Quality Manager and any other relevant member of staff will meet as soon as feasible to discuss the complaint and the appropriate response.
- 2.8 If appropriate, a telephone response to the complaint may be made by the Head of the Unit or the Quality Manager but in all cases a written response must also be made. A copy of the written response must be attached to the complaint record sheet.

- 2.9 If an error in the working of the Unit is revealed (individual or systemic) this will be reviewed at the earliest opportunity, either with selected members of staff or at a staff meeting, and corrective action taken.

3.0 **USER SURVEYS**

- 3.1 User surveys will be issued to a minimum of two clients annually, MDU-US1 to 3.
- 3.2 Surveys sent and completed will be recorded on record sheet RS127.
- 3.3 Survey feedback will be reviewed and recorded at annual MDU management meetings.

4.0 SUMMARY OF REVISIONS

VERSION NUMBER	DETAILS OF REVISION(S)	EFFECTIVE DATE
2	Addition of User Survey procedure	14/02/2020
3	Addition of timeline to address complaints	28/02/22
4	Addition of logging a NCQI when a complaint is received.	08/10/24
5	Addition of 2.5 on assessment of risk and clinical impact on patients	18/12/24

Review History

Scheduled review date	Actual review date	Reviewed by	Authorised	Actions
23/1/2010	22/2/2010	S. Kaye	M. McClure	None
22/2/2012	7/3/2012	S. Kaye	M. McClure	None
7/3/2014	1/8/14	S. Dustan	M. McClure	None
1/8/16	20/12/16	S. Dustan	M. McClure	None
20/12/18	7/2/19	S. Kaye	M. McClure	None
07/02/21	14/02/21	A. Badhan	M. McClure	None
14/02/22	18/01/22	A. Badhan	M. McClure	None
18/01/24	28/02/22	A. Badhan	G. P. Taylor	V3
28/02/24	28/02/24	A.Yang	G. P. Taylor	None
28/02/28	08/10/24	A.Yang	G. P. Taylor	V4-see summary above
28/02/28	18/12/24	A.Yang	G. P. Taylor	V5

