

5.9 → Release of reports

Have documented procedure for.

- Laboratory personnel who may release results are defined
- Person who may receive results are defined
- primary sample quality

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unsuitable for examination or
could have compromised the result.

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indicate in report.

- When examination results falls within established alert or critical intoway.

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① Notify physician or other authorized health professional immediately
(results received on samples sent to referral laboratories for examination)

② Maintain records of action taken

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Document date, time,
responsible laboratory staff member,
person notified,
Examination results conveyed
Any difficulties encountered in notification

→ Results — legible

- without mistakes in transcription
- Reported to person authorized to receive & use the information

for

→ Interview report → final report is always forwarded to requester.

→ Oral results → Record maintained of all oral results provided

- oral report shall be followed by written report
- documented process ensuring that results distributed by telephone or electronic means reach only authorized recipients

→ Certain genetic / Infectious disease examination

- Special counselling may be needed
- Results with serious implications are not communicated directly to patient without opportunity for adequate counselling

→ Results of laboratory examination separated from all patient identification may be used for epidemiology, demography or other statistical analyses

→ Automated selection & reporting of results

Documented procedure ensures that.

- Criteria - Defined
 - Approved
 - Readily available
 - understood by staff
 - Validated for proper functioning before use
- Verified after changes to system that might affect their functioning
- process for indicating sample interference presence like hemolysis, icterus, lipaemia that may alter results of examination
- process for incorporating analytical warning messages from instruments into automated selection & reporting criteria, when appropriate.
- Results shall be identifiable at time of review before release & includes date & time of selection
- process for rapid suspension of automated selection & reporting

→ Revised report

Written instruction regarding revision shall be written.

- Revised report is clearly identified as revision & includes reference to date & patient's identity in original report.
- user is made aware of revision
- Revised record shows - time & date of change
Name of person responsible for change
- original report entries remain in record when revision are made
- Results that have been made available for clinical decision making & revised shall be retained in subsequent cumulative reports & clearly identified as having been revised.
- when reporting system cannot capture amendments, changes or alteration, a record of such shall be kept.