Reporting

Reporting	
Former Standard and Guidance	***Revised Standard and Guidance***
Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results The requirements to authorize release of test results must be described in a standard operating procedure. The procedure must define staff that are authorized to release test results, as delegated in writing by the director. Standard operating procedures for automated verification and release of results must be approved by the director or individual delegated as responsible in writing by the director. In the categories of cytopathology and histopathology, only a licensed pathologist, practicing in the state where they are licensed, is authorized to release pathology reports, with the exception of negative gynecological cytopathology reports which may be released by a cytotechnologist. ***Regulatory authority: 10 NYCRR section 58-1.3 and subdivision 58-1.10(b) and (g)***	**Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results** The requirements to authorize release of test results must be described in a standard operating procedure. The procedure must define staff that are authorized to release test results, as delegated in writing by the director. Standard operating procedures for automated verification and release of results must be approved by the director or individual delegated as responsible in writing by the director. In the categories of cytopathology and histopathology, only a licensed pathologist, practicing in the state where they are licensed, is authorized to release pathology reports, with the exception of negative gynecological cytopathology reports which may be released by a cytotechnologist. ***Regulatory authority: 10 NYCRR section 58-1.3 and subdivision 58-1.10(b) and (g)*** **Guidance -** Supervisor qualified staff must verify that approved protocols are routinely followed by testing personnel who

Guidance - Supervisor qualified staff must verify that approved protocols are routinely followed by technologists who have been authorized to release results. Electronic signatures must be password protected.	have been authorized to release results. Electronic signatures must be password protected. Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required. Remote review of cytology digital slides is not permitted.

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Reporting Standard of Practice 2 (REP S2): Test Report Content Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a hard copy of a laboratory report. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the	**Reporting Standard of Practice 2 (REP S2): Test Report Content** Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a ~~hard~~ copy of a laboratory report that meets the below requirements. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g., “doing business as”);

laboratory has reported to the Department an alternative name (e.g., “doing business as”);	c) the date, and hour if required, when the specimen was collected;
c) the date, and hour if required, when the specimen was collected;	d) the test report date;
d) the test report date;	e) specimen type and/or source (i.e., anatomic location), when appropriate;
e) specimen type and/or source (i.e., anatomic location), when appropriate;	f) the test(s) performed
f) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values;	g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values;
g) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under Reporting Standard of Practice 1; or	i. Alternative mechanisms other than reporting these values on the report may be approved by the d(D)epartment;
i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and	h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under Reporting Standard of Practice 1; or
h) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation;	i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and
i) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported;	i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation;
j) any disclaimers or limitations to testing where required by the Department for an approved laboratory developed test (LDT);	j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported;
k) any additional information required for the interpretation of results; and	k) any disclaimers or limitations to testing where required by the Department for an approved laboratory developed test (LDT);
l) any other information as required in any part of the	l) any additional information required for the interpretation of results; and

New York State Clinical Laboratory Standards of Practice. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)***	m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. Report information, whether required or discretionary, must be accurate. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)*** **Guidance -** "a copy" of a laboratory report may be either electronic or hardcopy. j) The address of a remote location performing review of digital results under a laboratory's permit may be indicated on the final report by a code. The testing laboratory is responsible for maintaining a 'key' to correlate codes to addresses. l) Examples include: disclosure of the specific equation used for estimated Glomerular Filtration Rate (eGFR) for clinician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient populations.

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Reporting Standard of Practice 5 (REP S5): Timeliness When the laboratory cannot report patient test results within its established time frames, the laboratory must have a policy to determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	**Reporting Standard of Practice 5 (REP S5): Timeliness** When the laboratory cannot report patient test results within its established time frames, the laboratory must establish and follow a policy to determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***
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Reporting Standard of Practice 6 (REP S6): Alert Value The laboratory must immediately alert the authorized ordering source or client requesting the test and, if applicable, the individual responsible for using the test results, when any test result indicates an imminently life-threatening condition, or panic or alert values, according to protocols established in Test Procedure Content Standard of Practice 1. The laboratory must document the date, time, test results and person to whom the results were reported. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	**Reporting Standard of Practice 6 (REP S6): Alert Value** The laboratory must immediately alert the authorized ordering source or client requesting the test and, if applicable, the individual responsible for using the test results, when any test result indicates an imminently life-threatening condition, or panic or alert values, according to protocols established in Test Procedure Content Standard of Practice 1. The laboratory must document the date, time, test results and recipient to whom the results were reported. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***