

PCR and RT-PCR Acceptance and Retest Criteria

Verify External Controls		
Item	Acceptance Criteria	When Acceptance Criteria is not met...
NTC	(b) (4)	(b) (4) to evaluate the signal for the pathogen target detector in NTC
		If (b) (4) Then (b) (4)
NEC	(b) (4)	(b) (4) to evaluate the signal for the pathogen target detector in NEC
		If (b) (4) Then (b) (4)
Positive Control	(b) (4)	(b) (4)
		If (b) (4) Then (b) (4)

(b) (4)	<table> <tr> <td data-bbox="806 155 1201 162">If</td><td data-bbox="1201 155 1822 162">(b) (4)</td></tr> <tr> <td data-bbox="806 162 1201 172"></td><td data-bbox="1201 162 1822 172">(b) (4)</td></tr> </table>	If	(b) (4)		(b) (4)
If	(b) (4)				
	(b) (4)				

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Item	Acceptance Criteria	When Acceptance Criteria is not met...
(b) (4)		(b) (4)
	If	Then

Evaluate Patient Curves		When Acceptance Criteria is not met...	
Item	Acceptance Criteria	If	Then
(b) (4)	(b) (4)		(b) (4)

(b) (6)

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Review Results

Item

Acceptance Criteria

(b) (4)

When Acceptance Criteria is not met...

(b) (4)

Check current results against previous results from a failed run		
Item	Acceptance Criteria	When Acceptance Criteria is not met...
Compare current result from re-extracted or re-plated sample against the previous result (b) (4) may be used to verify previous result)	(b) (4)	(b) (4)
		If
		(b) (4) Then

(b) (4)

Check Important Comments		
Item	Acceptance Criteria	When Acceptance Criteria is not met...
Sample is 'Leaked or Leaked on'	(b) (4)	(b) (4)
		If
		(b) (4) Then

Check Source		
Item	Acceptance Criteria	When Acceptance Criteria is not met...
Exception testing (b) (4)	(b) (4)	(b) (4)
		If
		(b) (4) Then

(b) (4)

(b) (4)

Warnings

- The Viracor SARS-CoV-2 assay has not been FDA cleared or approved;
- The Viracor SARS-CoV-2 assay has been authorized by FDA under an EUA for use by the authorized laboratory: Viracor Eurofins Clinical Diagnostics Laboratory located at 1001 NW Technology Dr., Lee's Summit, MO, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests;
- The Viracor SARS-CoV-2 assay has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The Viracor SARS-CoV-2 assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.