Safety Communication رسالة سلامة

potential for False Results with SARS-CoV-2 & Influenza AB Tests

Device/ Product Description:	cobas® Liat® PCR System
Manufacturer:	Roche Molecular Systems, Inc.
Problem:	False positive results can occur due to two issues: • The assay tubes may sporadically leak, causing an obstructed optical path in the Liat analyzer, producing abnormal PCR growth curves. This could lead to invalid or erroneous positive results, particularly for the Flu B test. If a tube leak occurs, later testing runs may have an increased likelihood of false positive Flu B results. • Abnormal PCR cycling in the reaction tubes may also produce abnormal PCR growth curves, leading to erroneous results. The issue is sporadic and may be caused by multiple factors happening at the same time, such as hardware positioning, volume movement, and curve interpretation. This issue may cause false positive results for multiple analytes (Influenza A, Influenza B and/or SARS-CoV-2) in a single testing run. False positive results could lead to improper patient management. False positive results may also lead to unnecessary isolation and additional health monitoring, delayed diagnosis and treatment, and mis-allocation of resources used for surveillance and prevention for other infections or health conditions.
Recommendation /Actions:	• Make sure that this document is reached to the end-users. • Monitor for unexpected clusters of positive Flu B results, as this may indicate the cobas Liat System has experienced a tube leak. • Repeat tests when two or three analytes are positive. Different results on the repeat test may indicate abnormal PCR cycling. • Stop using the cobas Liat System and contact Roche if you suspect either of these two issues has occurred.

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If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:
NCMDR
Vigilance system
(19999) unified call center</td></tr>
<tr><td>Devices/Products photo:</td><td> 
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<tr><td>Authorized Representative Details</td><td>
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<tr><td>AR name:</td><td>Roche Diagnostics Saudi Arabia Limited</td></tr>
<tr><td>Assigned Contact Person:</td><td>Turki Bin Juraid</td></tr>
<tr><td>Mobile/Phone:</td><td>+(966) 545673111</td></tr>
<tr><td>Email:</td><td>rdsa.regulatory@roche.com</td></tr>
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