

Flags Displayed on Laboratory, Patient, and Quality Control Reports

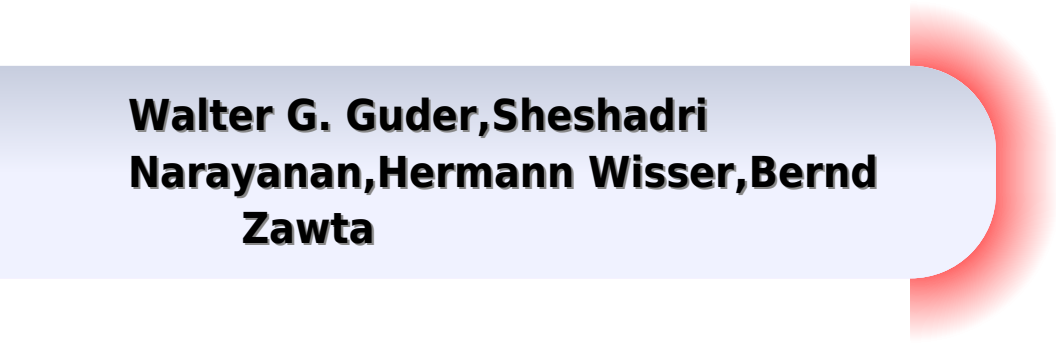
Important Note: Only the highest priority flag is printed, even if more than one flag might apply.

Flag	Description	Analyzer ¹	Condition	Suggested Actions ²
#	Modified Alternate Unit Selected	250	Indicates that a modified alternate unit has been selected.	No action necessary.
>	Above Analyzer Range	ALL	The result is above the analyzer range.	Quota the sample and repeat the test. Refer to the instructions for Use for more information.
>	Above Reportable Range	5,1 FS	The result is above the reportable range.	Quota the sample and repeat the test. Refer to the instructions for Use for more information.
<	Below Analyzer Range	ALL	The result is below the analyzer range.	Follow your laboratory procedures to report or repeat the test.
<	Below Reportable Range	5,1 FS	The result is below the reportable range.	Follow your laboratory procedures to report or repeat the test.
+	Outside Dynamic Range, Below Analyzer Range	250, 250AT, 350	The result is above or below the dynamic (reportable) range, but within the analyzer range.	Quota the sample and repeat the test. Refer to the instructions for Use for more information.
+2s	QC is more than 2 but less than or equal to 3 Standard Deviations above mean	5,1 FS	The control sample result is more than 2, but less than or equal to 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay Screens. If control results fall outside your acceptable ranges, investigate the cause prior to reporting test results.
-2s	QC is more than 2 but less than or equal to 3 Standard Deviations below mean	5,1 FS	The control sample result is more than 2, but less than or equal to 3 standard deviations below the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay Screens. If control results fall outside your acceptable ranges, investigate the cause prior to reporting test results.
+3s	QC is more than 3 Standard Deviations above mean	5,1 FS	The control sample result is more than 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay Screens. If control results fall outside your acceptable ranges, investigate the cause prior to reporting test results.
-3s	QC is more than 3 Standard Deviations below mean	5,1 FS	The control sample result is more than 3 standard deviations below the QC baseline mean.	Review control and analyte results on the Quality Control - Review by Assay Screens. If control results fall outside your acceptable ranges, investigate the cause prior to reporting test results.
+D	Above Dynamic Range	250, 250AT, 350	The result is above the dynamic (reportable) range, but within the analyzer range.	Quota the sample and repeat the test. Refer to the instructions for Use for more information.
-D	Below Dynamic Range	250, 250AT, 350	The result is below the dynamic (reportable) range, but within the analyzer range.	Follow your laboratory procedures to report or repeat the test.
+S	Outside Supplementary Range	250, 250AT, 350	The result is outside the user-defined supplementary range. For user-configurable ranges, refer to: OPTIONS, TESTFLUID CONFIGURATION.	Follow your laboratory established procedures.
+S	Above Supplementary Range	250, 250AT, 350	The result is above the user-defined supplementary range. For user-configurable ranges, refer to: OPTIONS, TESTFLUID CONFIGURATION.	Follow your laboratory established procedures.
+SR	Above Displacement Range	5,1 FS	The result is above the defined supplementary range for the analyte. For user-configurable ranges, refer to: V-DOCS, OPTIONS, CONF-SUPPLEMENTARY ADJUST.	Follow your laboratory established procedures.
-S	Below Supplementary Range	250, 250AT, 350	The result is below the user-defined supplementary range. For user-configurable ranges, refer to: OPTIONS, TESTFLUID CONFIGURATION.	Follow your laboratory established procedures.
-SR	Below Displacement Range	5,1 FS	The result is below the defined supplementary range for the analyte. For user-configurable ranges, refer to: V-DOCS, OPTIONS, CONF-SUPPLEMENTARY ADJUST.	Follow your laboratory established procedures.
+2	QC is at least 2 but less than 3 Standard Deviations	250, 250AT, 350	The control sample result is at least 2 but less than 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review and Edit QC. Repeat the test.
+3	QC is at least 3 Standard Deviations	250, 250AT, 350	The control sample result is at least 3 standard deviations above the QC baseline mean.	Review control and analyte results on the Quality Control - Review and Edit QC. Repeat the test.
H	High Result	ALL	The result is above the laboratory's defined reference interval for the analyte. For user-configurable ranges, refer to: OPTIONS, TESTFLUID CONFIGURATION. For 5,1 FS - refer to V-DOCS, OPTIONS, CONFIGURING ADJUST.	Follow your laboratory established procedures.
L	Low Result	ALL	The result is below the laboratory's defined reference interval for the analyte. For user-configurable ranges, refer to: OPTIONS, TESTFLUID CONFIGURATION. For 5,1 FS - refer to V-DOCS, OPTIONS, CONFIGURING ADJUST.	Follow your laboratory established procedures.
P	Pending Sample	250, 250AT, 350	Multiple sample-oriented test cannot be completed until both the pre-treated and untreated samples are run.	Run the appropriate pretreated or untreated sample.
22s	Two consecutive controls are 2 or more standard deviations above or below mean	5,1 FS	The control result is at least 2 standard deviations above or below the baseline mean for two consecutive controls.	Review control and analyte results on the Quality Control - Review by Assay Screens.
44s	Two consecutive controls changed at least 4 standard deviations	5,1 FS	The control result for two consecutive controls changed at least 4 standard deviations.	Review control and analyte results on the Quality Control - Review by Assay Screens.
41s	Four consecutive controls are 1 or more standard deviations above or below mean	5,1 FS	The control result is at least 1 standard deviations above or below the baseline mean for four consecutive controls.	Review control and analyte results on the Quality Control - Review by Assay Screens.
10s	Ten consecutive results are on the same side of the mean	5,1 FS	The control result for ten consecutive controls are on the same side of the mean.	Review control and analyte results on the Quality Control - Review by Assay Screens.

¹ ALL includes the VITROS 250, 250AT, 350, and 5,1 FS Chemistry Systems.
² Always follow your laboratory established procedures.
³ Displayed only when Reference Range Reporting is enabled.

Sample Lab Report Ortho Clinical Diagnostics 144526

**Walter G. Guder, Sheshadri
Narayanan, Hermann Wisser, Bernd
Zawta**



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