

University of Texas Medical Branch Pulmonary Function Clinic Policy 04-10 Westgard Rules	Effective Date: Revised Date: Review Date:	Aug 92 Oct 05 Aug 23
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Westgard Rules

Audience All personnel in the Pulmonary Function Clinics.

Purpose To explain the Westgard Rule Control Rules of quality control in detail.

Rule 1-2s *Definition:* The 1-2s Control Rule indicates one control result has exceeded the established mean \pm 2SD range. This is a “warning rule,” which does not indicate an “out-of-control” condition, but is intended to initiate further testing.

Interpretation: If no other control rule is violated, then the warning is attributed to normal random error. Patient results are acceptable.

Corrective Action: No corrective action is required. However, the “warning” suggests a system error may be in the development. A comprehensive check of the routine maintenance schedule and review of the quality control ampoule handling and sampling technique is recommended.

Rule 1-3s *Definition:* The 1-3s Control Rule indicates one control result has exceeded the established mean \pm 3SD range. This is a “rejection rule,” which is sensitive to random error.

Interpretation: Excessive random error exists. The analyzer is “out-of-control.” Patient results are not acceptable and should be re-analyzed after corrective actions have solved the problem.

Corrective Action: Rerun the quality control level that is in question, emphasizing proper technique. If the repeated level is within \pm 2SD range then the problem can be attributed to random error. If the repeated level exceeds the \pm 2SD range, then further corrective action should be conducted. The following are probable causes:

- Inadequate or wrong \pm 2SD range.
- Improper storage temperature correction of quality control results.
- Improper technique when handling the quality control.
- Change of quality control batch.
- Inadequate maintenance of the instrument.

Rule 2-2s *Definition:* The 2-2s Control Rule indicates that two consecutive control results have exceeded the same mean \pm 2SD limit. This is a “rejection rule,” which is sensitive to systematic errors.

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Interpretation: A systematic error exists. The analyzer is “out-of-control.” This may be an early indicator for a “shift” in the mean value. Patient results are not acceptable and should be re-analyzed after corrective action has solved the problem.

Corrective Action: To resolve systematic errors, corrective action should be conducted to address the following probable causes:

- Inadequate or wrong +/- 2SD range.
- Improper technique when handling the quality control.
- Improper storage temperature correction of the quality control results.
- Change of the quality control batch.
- Inadequate maintenance of the instrument.

Rule R-4s *Definition:* The R-4s Control Rule indicates that one result has exceeded the mean +/- 2SD limit and the adjacent result has exceeded the mean +/- 2SD limit. This is a “rejection rule,” which is sensitive to random error.

Interpretation: Excessive random error exists. The analyzer is “out-of-control.” Patient results are not acceptable and should be re-analyzed after corrective action has solved the problem.

Corrective Action: See Rule 1-3s.

Rule 4-1s *Definition:* The 4-1s Control Rule indicates four consecutive control results have exceeded the same mean +/- 1SD limit. This is a “rejection rule,” which is sensitive to systematic errors.

Interpretation: A systematic error exists. The analyzer is “out-of-control.” This may be an early indicator for a “shift” in the mean value. Patient results are not acceptable and should be re-analyzed after corrective action has solved the problem.

Corrective Action: See Rule 2-2s.

Rule 10-x *Definition:* The 10-x Control Rule indicates ten consecutive control results have fallen on the same side of the mean. This is a “rejection rule,” which is sensitive to systematic errors.

Interpretation: A systematic error exists. The analyzer is “out-of-control.” Patient results are not acceptable and should be re-analyzed after corrective action has solved the problem.

Corrective Action: See Rule 2-2s.

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This form documents the approval and history of the policies and procedures for the Pulmonary Function Laboratory. The Medical Director signs all policies verifying initial approval. Annually thereafter, the Director and/or designee may approve reviews and revisions.

Date	Approved by:	Signature
11/07	V. Cardenas, MD Medical Director Pulmonary Laboratory	
6/09	V. Cardenas, MD No changes to the policy	
7/10	V. Cardenas, MD No changes to the policy	
2/12	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to the policy	
04/14	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	
08/16	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	
11/17	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	
8/19	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	
8/21	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	
8/23	A. Duarte, MD Medical Director Pulmonary Laboratory No changes to policy	