ACCU-CHEK® and AccuData® Systems Evaluation Protocol

Meter-to-Meter Comparability Study Protocol for Glucose Meter Evaluations

Purpose of Protocol

This protocol is a guidance tool for performing meter-to-meter comparability studies and is recommended for use with the Roche ACCU-CHEK blood glucose monitoring systems.[1] If you wish to include other manufacturers' systems in your studies you should contact each vendor to obtain their recommended evaluation protocols.[2]

Introduction

Meter-to-meter comparability testing is a form of intermediate precision studies[3]. This protocol is designed to help you assess the closeness of agreement between independently performed tests using patient samples on all of your ACCU-CHEK blood glucose meter systems at the same time. While regulations vary on whether a demonstration of meter-to-meter comparability with blood is required for CLIA waived unit-use test methods such as point of care blood glucose meter systems, there is a long-standing regulatory interest in assessing the agreement of different or same type instruments using patient samples.[4,5]

The number of samples that should be included in a Meter-to-Meter Comparability Study is not mandated. For broad range coverage, this procedure suggests testing three samples in your study, one at a low glucose level (between 30 and 60 mg/dL), one at a mid level glucose level (between 250 and 325 mg/dL) and one at a high glucose level (between 450 and 550 mg/dL), however, you may chose to run fewer or more samples at whatever levels you deem appropriate. The **Meter-to-Meter Comparability Study Data Log Forms** at the end of this procedure will help you to establish the design of your study and record your data. You will find forms configured for three and five sample studies.

The common statistical indicators of meter-to-meter comparability are the inter-meter Standard Deviation (mg/dL) and Coefficient of Variation.

Factors to Consider

1. This procedure assumes that all meters used in the studies can be brought to a single location for the studies. Due to the effect of glycolysis, it is not possible to carry out this procedure if meters are distributed to various locations in your facility. The ideal time to perform this study is prior to placing a new system in service and before the meters have been distributed to their designated locations.
2. Due to logistical difficulties, some regulations and guidelines suggest other schemes for assessing meter-to-meter comparability. An example would be to perform meter-to-meter comparability testing with patient samples on a representative subset of meters and then use quality control materials to assess the comparability of your remaining meters.[6]
3. You can incorporate the element of method-to-method comparability into your meter-to-meter comparability studies by centrifuging each sample after you have tested it on all of your meters and then testing the plasma on your chemistry reference analyzer. In this case you can calculate the difference between each meter result and your reference analyzer result.
4. Do not use samples with obvious matrix abnormalities such as hemolysis, icterus, lipemia, extremely low or high hematocrit or high sedimentation rate for a Meter-to-Meter Comparability Study.
5. The Roche *Glucose Spiking Protocol for Glucose Meter Evaluations* can be used to help you achieve various glucose levels in the samples you choose for your study.
6. For efficiency, it is helpful to have your meters minimally configured for a Meter-to-Meter Comparability Study. For example, long sample ID's and forced comment codes will add steps and delay the processing of each sample.

Sample Requirements

Use anticoagulated whole blood samples for your Meter-to-Meter Comparability studies. Always refer to the ACCU-CHEK test strip package insert for specific information on what types of blood samples (venous, arterial, capillary or neonate) and anticoagulants may be used with each type of ACCU-CHEK test strip.

Safety Considerations

Follow all of your internally established biohazard / bloodborne pathogen safety procedures when handling and disposing of biological materials and sharps.
Do any new statements need to be added due to FDA recent feedback on cleaning / disinfecting?

Materials

Gather the following materials in preparation for your studies:

- ACCU-CHEK meters
- ACCU-CHEK test strips (The number of strip vials needed will vary depending upon the number of meters and samples included in your studies.)
- ACCU-CHEK Quality Control Solutions - Level 1 (Low) and Control Level 2 (High)
- Whole blood collected in tubes as allowed in the ACCU-CHEK test strip package insert.
- Transfer pipettes
- Countertop disinfectant
- Biohazard container
- Forms for recording results (see **Meter-to-Meter Comparability Study Data Log Forms Appendix** at the end of this procedure for sample forms)

Study Procedure

1. Calibrate each meter system for the test strip lot you will be using for your study. (If your meter system requires a Code Key for calibration, it is important to have pre-loaded the Code Key information into each study meter prior to executing this protocol. Attempting to add Code Keys information while running this protocol is cumbersome and time-consuming and may introduce interference from glycolysis.)
2. Perform quality control testing on all meters using the appropriate Roche ACCU-CHEK Quality Control Solutions. Proceed with testing only if control results are within range.
3. Gather supplies listed above and arrange all of your meters and supplies on a countertop for efficient testing. All meters must be laid out at the same time.
4. Prepare each meter for a test.
5. Apply blood to each meter using a transfer pipette. Testing should be performed on all of the meters in the study within a 5 minute period.
6. Optional Step: Centrifuge the sample and test the sample plasma on your chemistry plasma analyzer.
7. Record all results. The record of results should include the date of testing, meter serial numbers, reagent lot numbers and expiration dates and the identity of the operator performing the testing.
8. Repeat steps 3-6 on each sample you wish to include in your study.

Analysis of Results

1. Calculate the mean for each sample by adding all test results for each sample and dividing the total by the number of tests. The formula for calculating the mean is as follows:

$$Mean = \frac{\sum(X_i)}{N}$$

X_i = the value of each test
N = the total number of tests

2. Calculate the Standard Deviation (SD) for each sample according to the following formula:

$$1SD(mg/dL) = \sqrt{\frac{\sum\left(x_i - \bar{x}\right)^2}{N-1}}$$

x_i = the value of each test
$\bar{x}$ = the mean of the test
N = the total number of replicate test

3. Calculate the Coefficient of Variation (CV) according to the following formula:

$$CV(\%) = \frac{SD}{\bar{x}} \times 100$$

4. Calculate meter bias from reference analyzer as follows:
   For reference analyzer glucose values less than 75 mg/dL, subtract the reference value from the meter value.

   Meter Value (mg/dL) – Reference Value (mg/dL) = Difference (mg/dL)

   For reference analyzer glucose values greater than or equal to 75 mg/dL, subtract the reference value from the monitor value. Divide the difference by the reference value. Multiply the result by 100 to obtain the % difference

$$\left(\frac{MeterValue(mg/dL) - ReferenceValue(mg/dL)}{ReferenceValue(mg/dL)}\right) \times 100 = \%Difference$$

5. Evaluate the results for acceptability according to your established acceptability criteria.

Procedure Notes

1. Call the Roche ACCU-CHEK Customer Care line at 1-800-440-3638 if you observe any unexpected results.
2. A common recommendation is to evaluate precision based on SD for sample means below 75 mg/dL and based on CV for sample means greater than or equal to 75 mg/dL. This eliminates the mathematical exaggeration of percentages at low glucose levels.[7]

Appendices

Meter-to-Meter Comparability Study Data Log Form

Hospital Name: _____

Date of Study: _____

Performed by: _____

	Controls			Whole Blood		
Serial #	**Low**	**Hi**		**Level 1**	**Level 2**	**Level 3**
Reference Analyzer Results						

ACCU-CHEK Test Strip Lot: _____ Expiration: _____

ACCU-CHEK Control Lot: _____ Expiration: _____

Meter-to-Meter Comparability Study Data Log Form

Hospital Name: _____

Date of Study: _____

Performed by: _____

	Controls			Whole Blood				
Serial #	**Low**	**Hi**		**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
Reference Analyzer Results								

ACCU-CHEK Test Strip Lot: _____ Expiration: _____

ACCU-CHEK Control Lot: _____ Expiration: _____

References

[1] All ACCU-CHEK products must be used according to their labeling. All evaluation protocols are supplemental to proper use as described in each system's packaging.
[2] CLSI C30A-2; Point of Care Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline-Second Edition; 2002; Item 6.3.2.1.2; Page 7
[3] ISO 15197, *In Vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003, Section 3.11, page 3.
[4] Clinical Laboratory improvement amendments of 1988; Final Rule. Federal Register. 2003 (January 24):3712 [42CFR493.1281(a)].
[5] CLSI C54-A; Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline; Vol. 2; No. 19; Item 5, Page 5.
[6] CLSI C54-A; Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline; Vol. 2; No. 19; Item 5, Page 20.
[7] ISO 15197, *In Vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003, Sections 7.2.4, page 18.

General Information

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