ACCU-CHEK® and AccuData® Systems Evaluation Protocol

Precision Studies Protocol for Glucose Meter Evaluations

Purpose of Protocol

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

Introduction

Precision studies are a way of demonstrating and measuring the closeness of agreement between independently performed tests on the same sample under defined conditions.[3,4] Precision studies are conducted by performing replicate tests of the same sample on the system being evaluated. A measurement system's precision is the extent to which the replicate tests agree with one another. Precision studies should be performed at a minimum of two different levels within the analytical measurement range of the system. The levels tested should represent normal and abnormal glucose values and it may be beneficial to consider targets that represent other medical decision levels.[5,6] The common statistical indicators of precision are Standard Deviation (mg/dL) and Coefficient of Variation (%), which is the SD expressed as a percentage of the mean. The relationship between the precision and the size of the SD and CV is inverse, meaning that the lower the SD's and CV's, the stronger precision.[7]

Factors to consider

There are numerous variables that can affect the outcome of a precision study and the size of the SD and CV. Common variables are different operators, different meters, different locations and the length of time over which you carry out your testing. Precision studies may be performed in a way that includes or excludes these variables. A precision study performed by a single operator in one analytical run is called a within-run or repeatability[8] study and will most closely reflect the inherent precision of the system being studied. This is a good baseline type precision study.[9] A study that includes additional and possibly different variables is called a between-run or intermediate precision study. This type of study will show somewhat weaker precision, but will more closely reflect the precision of the system under typical conditions of use. What variables to include in your studies will depend upon what you want to know about the impact of individual variables. For example, if you want to see how different meters impact precision, you should design your study to include a number of different meters. If you want to see how precision is impacted over time, you should perform your testing over a number of days. The **Precision Study Data Log Forms Appendix** at the end of this procedure will help you to establish the design of your study and plan the inclusion or exclusion of variables.

Sample Requirements

Precision studies may be performed using the ACCU-CHEK glucose control / linearity solutions or whole blood samples. Always refer to the ACCU-CHEK test strip package insert for specific information on what types of controls, blood samples (venous, arterial, capillary or neonate) and anticoagulants may be used with each type of ACCU-CHEK test strip. The Roche *Glucose Spiking Protocol for Glucose Meter Evaluations* provides instructions for spiking whole blood samples if needed to obtain high glucose levels. Only within-run studies can be performed using whole blood due to the effect of glycolysis in whole blood over time. Precision studies using controls / linearity solutions can be carried out over a number of hours or days (between-run).

Safety Considerations

Follow all of your internally established biohazard / bloodborne pathogen safety procedures when handling and disposing of biological materials and sharps.

Materials

Gather the following materials in preparation for your studies:

- ACCU-CHEK meter(s)
- ACCU-CHEK test strips (The number of test 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)
- Samples:
    - ACCU-CHEK glucose control / linearity solutions, or;
    - Whole blood collected in tubes as allowed in the ACCU-CHEK test strip package insert. Transfer pipettes, countertop disinfectant and a biohazard container will be needed if you are testing whole blood.
- Forms for recording results (see **Precision Study Data Log Forms Appendix** at the end of this procedure for sample forms).

Study Procedure

1. Perform quality control testing using the Roche ACCU-CHEK Quality Control Solutions (Level 1 and Level 2). Proceed with testing only if control results are within range.
2. Gather supplies listed above and arrange meters and supplies on a countertop for efficient replicate testing. If you are performing a study that will take place over a number of days you will want to consider using space that can be left undisturbed over the period of the study.
3. Perform a minimum of 20 replicate tests on each sample to be tested.[10] The 20 replicate tests could be performed on each meter, or distributed over multiple meters. If you are testing whole blood, the twenty replicates tests must be completed within a 30 minute period to minimize the impact of glycolysis on your results.

4. 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.

Analysis of Results

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

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

Xi = the value of each replicate test
N = the total number of replicate tests

2. Calculate the Standard Deviation (SD) for each series of replicate tests 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 replicate test
$\bar{x}$ = the mean of the series of replicate tests
N = the total number of replicate tests

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

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

4. 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.[11]

Appendices

ACCU-CHEK Evaluation Protocol
Within-Run Precision Study Collection Form

Hospital Name: _____
Date of Study: _____
Performed by: _____

Level_____					
Replicate Test	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Mean					
SD, mg/dL					
CV, %					

Level_____					
Replicate Test	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Mean					
SD, mg/dL					
CV, %					

ACCU-CHEK Test Strip Lot: _____ Expiration: _____
ACCU-CHEK Control Lot: _____ Expiration: _____

ACCU-CHEK Evaluation Protocol
Within-Run (Repeatability) Precision Study Collection Form

Hospital Name: _____
Date of Study: _____
Performed by: _____

Level _____

Replicate Test	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
Mean					
SD, mg/dL					
CV, %					

ACCU-CHEK Test Strip Lot: _____ Expiration: _____
ACCU-CHEK Control Lot: _____ Expiration: _____

ACCU-CHEK Evaluation Protocol
Between-Run (Intermediate) Precision Study Collection Form

Hospital Name: _____
Date of Study: _____
Performed by: _____

Level _____

Test Date	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Meter Serial # _____	Tech
Mean						
SD, mg/dL						
CV, %						

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] Westgard QC, Glossary of Terms http://www.westgard.com/glossary.htm#p, accessed August 2011.
[4] CLSI EP15-A2, User Verification of Performance for Precision and Trueness; Approved Edition, 2nd Edition, 2006, page 3
[5] Basic Method Validation, 3nd Edition; James O. Westgard, Ph.D.; Copyright 2008; Westgard QC, Inc.; Madison, WI; page 117.
[6] CLSI EP15-A2, User Verification of Performance for Precision and Trueness; Approved Edition, 2nd Edition, 2006, Section 7.3, page 6
[7] ISO 15197, *In Vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003, Section 3.19, page 4.
[8] ISO 15197, *In Vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003, Sections 3.21-3.22, page 4ff.
[9] Basic Method Validation, 3rd Edition; James O. Westgard, Ph.D.; Copyright 2008; Westgard QC, Inc.; Madison, WI; page 115.
[10] Basic Method Validation, 3r3d Edition; James O. Westgard, Ph.D.; Copyright 2008; Westgard QC, Inc.; Madison, WI; pages 114, 285.
[11] 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

This document is published by the Roche Diagnostics Commercial Education department.
Questions or comments regarding the contents of this guide can be directed to:

Roche Diagnostics
Commercial Education Department
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457
USA

This document is only available on the www.poc.roche.com website.

4480-00-1112

Revision History

Revised pages for this manual are provided by Roche Diagnostics when necessary. No part of this publication may be reproduced in any form or by any means without prior written permission.

Publication Reference Number	Date	Pages Affected
4480-00-1112	**November 2012**	**New document**