



# **ACCU-CHEK<sup>®</sup> and AccuData<sup>®</sup> Systems Evaluation Protocol**

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## **Glucose Spiking Protocol for Glucose Meter Evaluations**

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## Purpose of Protocol

The purpose of this protocol is to enable professional users of ACCU-CHEK blood glucose monitoring systems<sup>1</sup> to add concentrated glucose spiking solution to aliquots of whole blood to obtain high glucose values when performing method-to-method comparison studies and other product performance characteristics testing.<sup>2</sup> This protocol is intended for use in the context of method validation/verification studies and is supplemental to the Roche ACCU-CHEK accuracy and precision study protocols.

## Materials

### Preparation of 20% Dextrose Spiking Solution

#### Primary Method: (from analytical grade D-Glucose powder)

1. Gather the following items:
  - Analytical Grade D-Glucose powder
  - 100 mL volumetric flask
  - 0.9% saline
  - Stir Bar and stir plate
  - Parafilm<sup>®</sup> M3
2. Place 20 grams of analytical grade D-glucose into the 100 mL volumetric flask.
3. Fill flask to the 100 mL line with 0.9% (normal) saline.
4. Add the stir bar, cover the flask with parafilm and mix on the stir plate for 2 hours at room temperature.
5. Aliquots of this solution can be stored for future use in small tubes in the freezer for one year from the date they are prepared. Label the aliquots according to your reagent labeling policies.

#### Secondary Method: (From 50% Dextrose IV solution)

1. Gather the following items:
  - One 5 - 10 mL tube with a leak-proof cap.
  - Two 5 mL volumetric pipettes
  - 0.9% saline
  - One vial or bag of 50% dextrose in saline (commonly available as an IV product from Pharmacy or Central Supplies)
2. Pipette 3 mL 0.9% saline into the tube.
3. Pipette 2 mL of 50% dextrose in saline solution into the tube with 3 mL 0.9% saline.
4. Allow the tube to mix on a rocker for 20 minutes before using.
5. Aliquots of this solution can be stored for future use in small tubes in the freezer for one year from the date they are prepared. Label the aliquots according to your reagent labeling policies.

## Materials Needed for Preparing Spiked Samples

1. 5-7 mL whole blood sample(s) collected in heparin or EDTA tubes. Samples selected for spiking should not demonstrate any obvious matrix abnormalities such as very low or high hematocrit, icterus, lipemia or hemolysis.
2. Approximately 5 mL plastic transfer tubes with leakproof caps
3. 10 microliter ( $\mu\text{L}$ ) pipettor with tips
4. One (1) mL pipettor with tips
5. 20% glucose spiking solution prepared by one of the methods described above
6. ACCU-CHEK blood glucose meter systems

## Preparing Spiked Whole Blood Samples and Performing Meter-to-Lab Analyzer Comparison Testing

1. Select a whole blood sample that you intend to spike. (Several samples can generally be processed at the same time.)
2. Perform a meter test on the sample so that you know what the baseline glucose level is in the sample. If possible, choose a sample with baseline glucose value that is somewhat elevated in order to minimize the amount of spiking solution you will need to add.
3. Transfer a 1, 2, 3 or 4 mL aliquot of the sample you have selected to spike into a secondary plastic tube with a leak-proof cap.
4. Determine approximately how high you want to raise the glucose level in the sample. Add 10  $\mu\text{L}$  increments of spiking solution to the aliquot(s) of blood to achieve the desired glucose level keeping in mind that each 10 $\mu\text{L}$  increment of spiking solution will raise the glucose level of the sample aliquot by the amount indicated in the following chart (values are approximate):

Sample Aliquot Volume	Approximate Increase in Glucose
1 mL	200 mg/dL
2 mL	100 mg/dL
3 mL	67 mg/dL
4 mL	50 mg/dL

**Example:** If you have a 2 ml sample aliquot with a baseline glucose value of 150 and you add two 10 $\mu\text{L}$  increments (20  $\mu\text{L}$ ) of spiking solution, the glucose level in the sample aliquot will rise to approximately 350 mg/dL.

5. After you have spiked the sample with the appropriate amount of solution, mix the sample by alternately rocking for 5 minutes and then allowing the sample to sit undisturbed for 5 minutes for a total of 30 minutes.
6. After mixing, test the whole blood spiked sample on your meter system.
7. Centrifuge the sample and test the plasma on the Laboratory Chemistry analyzer. The sample should be centrifuged and the plasma removed for chemistry analyzer

testing within 30 minutes of meter testing in order to minimize the effects of glycolysis.

## Procedure Notes

1. Test low and high controls on all meters and strip lots intended for use in your study. Do not use meters or strips that show QC results outside established limits.
2. Make a notation on your data log sheet designating which samples in your study are spiked.
3. Keep in mind that when you are performing a method-to-method correlation study, a good guideline is that glucose values should be spread throughout the reading range of the meter system and about 50% of your results should fall outside the normal range.<sup>4</sup> Spike as many samples as necessary to obtain a good representation of high glucose levels in your study. Samples may be allowed to glycolyze at room temperature or in a 37° C incubator up to 6 hours to achieve low glucose values.<sup>5</sup>
4. This spiking protocol may be used to perform whole blood linearity testing. In order to avoid matrix-related variability, it is important to spike aliquots of the same sample to all desired levels when performing whole blood linearity testing.
5. Refrigerated samples should not be used due to the possibility of red blood cell clumping in the sample from cold agglutinins.<sup>6</sup>

## References

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<sup>1</sup> All ACCU-CHEK products must be used according to their labeling with regard to sample requirements, therefore this spiking procedure cannot be used with products that are not designed to measure venous blood glucose.

<sup>2</sup> CLSI Document C30-A2, Point of Care Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline-Second Edition; 2002; Item 6.3.2.1.2; Page 7.

<sup>3</sup> Parafilm® M is a registered trademark of American National Can Company, USA.

<sup>4</sup> CLSI Document EP9-A2-IR, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Interim Revision Edition; 2002; Page 1.

<sup>5</sup> CLSI Document C30-A2, Point of Care Glucose Testing in Acute and chronic Care Facilities; Approved Guideline-Second Edition; 2002; Item 6.3.2.1.2; Page 7.

<sup>6</sup> Bryant, N; Laboratory Immunology and Serology, Revised Edition; W. B. Saunders Co.; 1992; Page 193 &194.

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