

Lithium System

The Lithium System is cleared for use in the moderate complexity laboratory setting. Please review all product literature prior to initiating use to ensure that recommended testing and quality control procedures are followed and appropriate safety precautions are taken.

IVD For In Vitro Diagnostic Use.



1 Prepare the Reader



Figure 1

1. Turn the Reader on by pressing the switch located on the left side of the unit. The Reader will display "Remove Cuvette Press RUN." Remove Cuvette Cover and check that the Cuvette Holder is empty. Replace Cuvette Cover and press down to ensure that it is firmly seated. Press the Run button. Confirm that the Reader display reads "Insert Reagent Blank-Press RUN" (Figure 1).



Figure 2

2. Gather together a Separator, Bulb Pipette, and a Reagent Pouch.

3. Place the Separator on a level surface, parallel to the right side of the Reader. Ensure that the yellow blood well is facing front. Gently place the Bulb Pipette into the hole just behind the yellow blood well. The Bulb Pipette will remain upright. Position the Separator approximately 2 to 3 inches from the Reader, making sure that the Bulb Pipette is positioned directly in line with the Side Light (Figure 2).

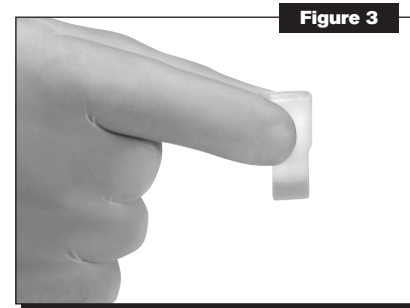


Figure 3

4. Open the Reagent Pouch and grasp the Cuvette from the top portion *only* throughout the procedure (Figure 3) (this will avoid any marks on the cuvette that will be in the light path and could affect the result).

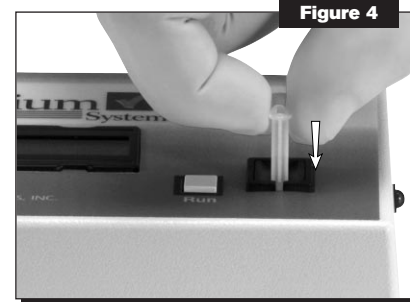


Figure 4

5. Peel back and remove the seal on the Cuvette. Tap the Cuvette on the table to ensure all reagent is down to the bottom. Remove the Cuvette Cover and insert the Cuvette into the Reader by aligning the flange on the Cuvette with the slot located in the front of the Cuvette Holder and pushing down firmly until seated (Figure 4).

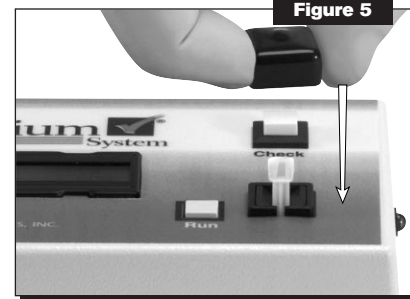


Figure 5

6. Replace the Cuvette Cover and press down to ensure that it is firmly seated (Figure 5). Press the Run button (Figure 6). In about 15 seconds the display will read "Insert Sample Press RUN."

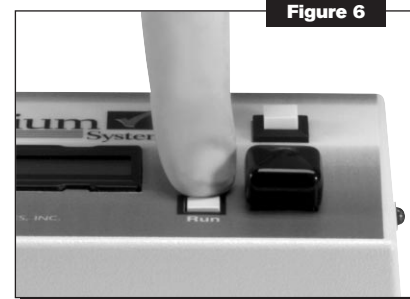

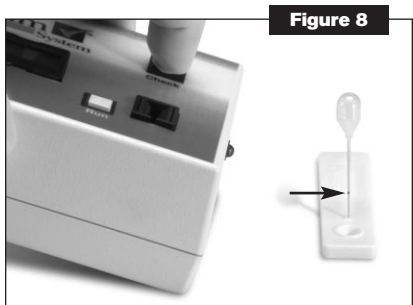
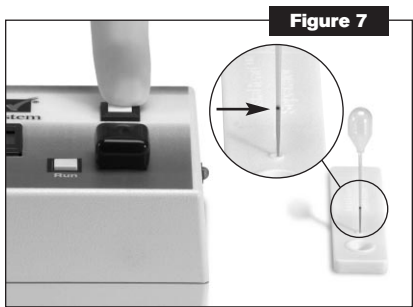


Figure 6

2 Obtain Patient's Test Sample

Note: The Lithium  System requires a 50 μ L patient sample of FRESH fingerstick or venous whole blood (EDTA), serum, or EDTA plasma. Venous whole blood (EDTA) samples must be tested within 4 hours of collection. Do not use frozen specimens.

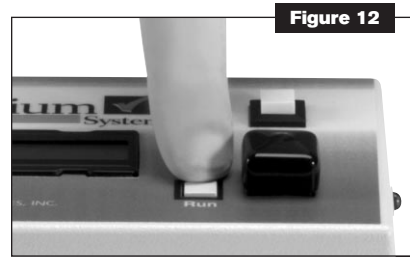
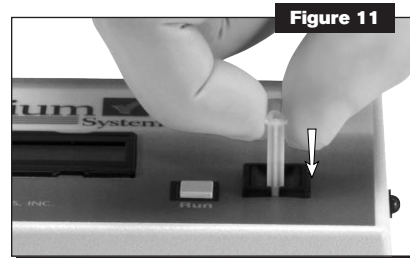
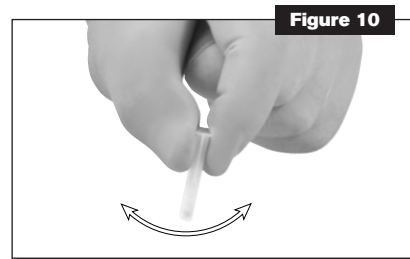
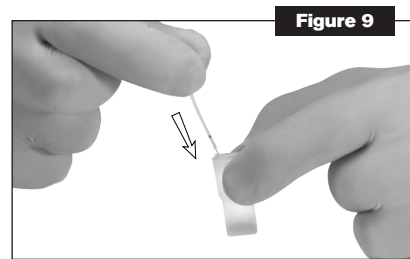
1. When the appropriate test sample volume is obtained, add the entire specimen to the yellow well on the Separator.
2. Wait approximately 1 minute, then press and hold the Check button on the Reader (Figure 7). A light will shine from the side of the Reader onto the shaft of the Bulb Pipette. Do not look directly at the light. Be sure that the green indicator reaches the black mark (arrow) before removing the Bulb Pipette. Continue to press the Check button at 5 – 10 second intervals until the green indicator reaches the black mark. (This step is complete when the green indicator reaches the black mark on the Bulb Pipette shaft.)




Note: Visibility of the green indicator can be enhanced by tilting the reader to angle the light path onto the lower end of the Bulb Pipette shaft (Figure 8) or moving the Separator closer to the light, lifting the Separator assembly directly into the light path.

3

Process the Sample



1. Remove Cuvette Cover and Cuvette from the Reader. Remove the Bulb Pipette from the Separator and completely immerse the tip into the reagent solution in the Cuvette (Figure 9).
2. Hold the Cuvette from the top at about eye level. Firmly squeeze and hold the Bulb to add the sample to the Cuvette. **Bubbles will appear.** Keep squeezing the Bulb and withdraw the Pipette from the Cuvette to ensure that none of the reagent is drawn back into the Pipette.
3. Shake the Cuvette quickly from side-to-side to ensure mixing (Figure 10).
4. Insert the Cuvette into Reader by aligning the flange on the Cuvette with the slot located in the front of the Cuvette Holder and pushing down until firmly seated (Figure 11).
5. Replace Cuvette Cover and press down to ensure that it is firmly seated. Press the Run button (Figure 12). The Reader will display the calculated lithium level in mEq/L. Record the value. Once the result is recorded, remove the cuvette from the Reader and dispose of all test materials. Press the Run button to prepare the Reader for the next test cycle.

For technical assistance, product information, or to order the Lithium  System and other Akers Biosciences products please call 1-800-451-TEST.

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