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## SBM TROUBLE-SHOOTING

| PROBLEMS               | POSSIBLE MISTAKES AND REASONS   |
|------------------------|---|
| Running too slow       | <ul> <li>Specimen:</li> <li>1. The nature/characteristic of the specimen gives interference (e.g. high viscidity, high bilirubin in blood)</li> <li>3. For blood specimens: hemolytic reaction caused by freezing and thawing repeatedly</li> <li>Operation Mistakes:</li> <li>1. The test was exposed in the air over one hour without temperature or humidity control.</li> <li>2. Did not operate according to the package insert , or the test has expired.</li> <li>3. Insufficient specimen added</li> </ul>  |
| Red running background | 1. Running too slow   |
| No flow or Leaking     | <ol> <li>Insufficient specimen applied.</li> <li>Too much specimen applied, flooding problem.</li> </ol>  |
| False positive         | <ul> <li>Before you investigate the reason, please make sure the specimen is a true negative by retesting with another test.</li> <li>Specimen interference: <ol> <li>Incorrect specimen type</li> <li>Cross reaction due to interference substances.(e.g. HAMA /RF /Pregnant blood cross reaction)</li> <li>The nature/characteristic of the specimen gives interference (e.g. high viscidity, high bilirubin)</li> </ol> </li> <li>Operation mistakes: <ol> <li>Incorrect operation in specimen collection.</li> <li>Did not operate according to the package insert.(for example the specimen exceed to the maximum line (MAX) of the strip when immersing the dipstick.)</li> <li>Inappropriate Pipette used</li> <li>Too much specimen applied.</li> </ol> </li> </ul> |
|                        | <ul> <li>5 .Insufficient specimen applied</li> <li>6. Device was moved before testing completed</li> <li>7. Incorrect read time</li> <li>8. Fail to interpret the result according to the package insert.</li> </ul>  |



|                | 9. The test is contaminated by the user, biological or chemical contamination   |
|----------------|---|
|                | 10. Running too slow.   |
|                | Storage mistakes:   |
|                | 1. The storage temperature is too high or too low of the test strip, reagents,  |
|                | and/ or controls  |
|                | 2. Lack of suitable storage and transportation conditions for the kit           |
|                | 3. Inadequate packaging (contamination and/or breakage)                         |
|                | Before you investigate the reason, please make sure the specimen is a true      |
|                | positive by retesting with another test.  |
|                | Specimen:   |
|                | 1. The concentration of test specimen was lower than detection limit.           |
|                | 2. Incorrect specimen type  |
|                | 3. Cross reaction due to interference substances. (e.g. HAMA/RF/Pregnant        |
|                | blood cross reaction)   |
|                | 4. The nature/characteristic of the specimen gives interference (e.g. high      |
|                | viscidity, high bilirubin)  |
|                | Operation mistakes:   |
|                | 1. Incorrect operation in specimen collection.                                  |
|                | 2. Did not operate according to the package insert. (for example the            |
|                | specimen exceed to the maximum line (MAX) of the strip when immersing           |
|                | the dipstick.)  |
| False negative | 3.Inappropriate Pipette used  |
|                | 4. Too much specimen applied.   |
|                | 5 .Insufficient specimen applied  |
|                | 6. Device was moved before testing completed                                    |
|                | 7. Incorrect read time  |
|                | 8. Fail to interpret the result according to the package insert.                |
|                | 9. The test is contaminated by the user, biological or chemical                 |
|                | contamination.  |
|                | 10. Running too slow.   |
|                | Storage mistakes:   |
|                | 1. The storage temperature is too high or too low for the test strip, reagents, |
|                | and/ or controls  |
|                | 2. Lack of suitable storage and transportation conditions for the kit           |
|                | 3. Inadequate packaging (contamination and/or breakage)                         |
|                |   |



| Invalid             | 1.Specimen is not enough  |
|---------------------|---|
|                     | 2. The test has expired.  |
| Weaker control line | 1. Not suitable specimen, (e.g. PH value is not suitable)                   |
|                     | 2. Too much specimen added into the sample well of the test cassette or the |
|                     | surface of liquid pass the "MAX" line printed on the strip label.           |