# Manufacturer Information

Quidel Corporation  
2005 East State Street, Suite 100  
Athens, OH 45701  
Phone: 1.800.874.1517  
Fax: 1.740.592.9820  
Emergency #: 1.866.519.4752  
Web: guidel.com  
E-mail: qehs@quidel.com

# Product Information

**Product Name:** MicroVue Bb Plus Fragment EIA kit (Catalog #: A027)  
**Intended Use:** The MicroVue Bb Plus Fragment Enzyme Immunoassay (EIA) measures the amount of the complement fragment Bb, an activation fragment of Factor B of the alternative pathway of complement, in human plasma or serum. This kit is for in vitro diagnostic use.  
**Components:** Bb Plus Standards A - E, Bb Plus Low Control (lyophilized), Bb Plus High Control (lyophilized), Microassay Plate, Stop Solution, 20X Wash Solution Concentrate, Complement Specimen Diluent, TMB Substrate, Bb Plus Conjugate and Hydrating Reagent.

# Classification of Substance or Mixture

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
</table>
| Stop Solution (4% Hydrochloric Acid) | Irritant | Eyes and Skin | Skin Irritation (Category 2)  
Eye Irritation (Category 2) |
| 20X Wash Solution, Complement Specimen Diluent, Hydrating Reagent (0.035% Proclin 300) | Irritant | Skin | Skin Sensitizer (Category 1) |
| TMB Substrate (Proprietary Mixture) | Irritant | Eyes, and Reproductive | Eye Irritation (Category 2A)  
Reproductive Toxicity (Category 1B)  
STOT SE (Category 3) |

# GHS Label Elements, Including Precautionary Statements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
</table>
| Stop Solution (4% Hydrochloric Acid) | ![Warning] | H315 Causes skin irritation.  
H319 Causes serious eye irritation. | P264 Wash hands thoroughly after handling.  
P280 Wear protective gloves and safety glasses.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| 20X Wash Solution, Complement Specimen Diluent, Hydrating Reagent (0.035% Proclin 300) | ![Warning] | H317 May cause an allergic skin reaction. | P264 Wash hands thoroughly after handling.  
P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water.  
P333+P313: If skin irritation or rash occurs: Get medical attention. |
### Section 2 – Hazards Identification (cont’d)

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
</table>
| TMB Substrate (Proprietary Mixture) | ![Danger] | H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.  
H360 May damage fertility or the unborn child. | P264 Wash hands thoroughly after handling.  
P280 Wear protective gloves and safety glasses.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

**Supplemental Hazard Statements**

1. Follow Universal Precautions when working with this kit. Refer to additional Universal Precaution information in Section 7, Handling and Storage.  
2. Avoid release to the environment.

### Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Component Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution (A9947)</td>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>&lt;4</td>
<td>12 mL</td>
</tr>
</tbody>
</table>
| TMB Substrate (5059)             | Hydrogen Peroxide  
1-Ethyl-2-Pyrrolidnone (NEP)  
Acetone                         | 7722-84-1  
2687-91-4  
67-64-1                         | 231-765-0  
220-250-6  
200-662-2                      | <0.1  
1 - 5  
1 - 10                       | 12 mL            |
| 1. 20X Wash Solution (A9957)     |                                         |         |          |            |                  |
| 2. Complement Specimen Diluent (A3670) |                                         |         |          |            |                  |
| 3. Hydrating Reagent (A3675)     |                                         |         |          |            |                  |
| **Mixture for Proclin 300:**     |                                         |         |          |            |                  |
| 5-Chloro-2-methyl-2, 3-        |                                         |         |          |            |                  |
| dihydroisothiazol-3-one; 2-     |                                         |         |          |            |                  |
| Methyl-2, 3-dihydroisothiazol-3-|                                         |         |          |            |                  |
| one (3:1)                       |                                         |         |          |            |                  |
|                                 |                                         | 55965-84-9 | No data  | 0.035     | 1. 50 mL  
2. 50 mL  
3. 25 mL |

### General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

**If inhaled:** Move the person to fresh air and support breathing as required.  
**In case of skin contact:** Wash affected area with soap and water. Seek medical advice if irritation develops.  
**In case of eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.  
**If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops. **TMB Substrate or Stop Solution:** Do not induce vomiting.  
**Note to Physicians:** Treat symptomatically.
Section 5 – Fire Fighting Measures

General Advice
Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

Extinguishing Media: For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
General Fire Hazards: The components within this kit will not significantly contribute to the intensity of a fire.
Hazardous Combustion Products: No data available
Fire Fighting Equipment: Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice
Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

Personal Precautions: Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

Materials and Methods for Clean-Up: Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.

Recovery and Neutralization: Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.

Environmental Precautions: Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: Refer to product specific Package Insert.

Precautions for Safe Handling
As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

Universal Precautions
No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.
Incompatibilities To maintain efficacy, store according to the kit specific Package Insert instructions.
Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific components within this kit.

Exposure Controls:

Engineering Measures: Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Hand Protection: Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

Eye Protection: Wear safety glasses with side shields or goggles to prevent eye contact.

Skin and Body Protection: Use body protection appropriate for the task. A laboratory coat is recommended.

Hygiene Measures: Wash hands before and after use and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stop Solution (A9947)</th>
<th>20X Wash Solution (A9957)</th>
<th>Complement Specimen Diluent (A3670)</th>
<th>TMB Substrate (5059)</th>
<th>Hydrating Reagent (A3675)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>&lt;1</td>
<td>6.1 to 6.6</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>Clear liquid, odorless</td>
<td>Slightly brown liquid, odorless</td>
<td>Clear liquid, mild odor</td>
<td>Clear liquid, odorless</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stop Solution (A9947)</th>
<th>20X Wash Solution (A9957)</th>
<th>Complement Specimen Diluent (A3670)</th>
<th>TMB Substrate (5059)</th>
<th>Hydrating Reagent (A3675)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>MW4025000</td>
<td>Oral LD₅₀</td>
<td>Rabbit</td>
<td>900 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC₅₀</td>
<td>Mouse</td>
<td>1108 PPM/1H</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD₅₀</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Mixture for Proclin 300:</td>
<td>55965-84-9</td>
<td>Not available</td>
<td>Oral LD₅₀</td>
<td>Rat</td>
<td>53 mg/kg</td>
</tr>
<tr>
<td>5-Chloro-2-methyl-2, 3-</td>
<td></td>
<td></td>
<td>Inhalation LC₅₀</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>dihydroisothiazol-3-one; 2-Methyl-</td>
<td></td>
<td></td>
<td>Dermal LD₅₀</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>2, 3-dihydroisothiazol-3-one (3:1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMB Substrate (proprietary mixture)</td>
<td>--</td>
<td>Not available</td>
<td>Oral LD₅₀</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC₅₀</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD₅₀</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

Potential Health Effects: Stop Solution (A9947) and TMB Substrate (5059) – Irritant
20X Wash Solution (A9957), Complement Specimen Diluent (A3670), and Hydrating Reagent (A3675) – Sensitizer

Skin Corrosion/ Irritation: No data available
Inhalation: May cause respiratory tract irritation.

Serious Eye Damage / Irritation: No data available
Skin: May cause skin irritation upon contact.

Respiratory or Skin Sensitization: No data available
Eyes: May cause serious eye irritation.

Generative Cell Mutagenicity: No data available
Ingestion: May be harmful if swallowed.

Carcinogenicity

No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, NTP or OSHA.

IARC: 3 – Group 3: Not classifiable as to its carcinogenicity to humans (Hydrochloric acid)

Reproductive Toxicity

TMB Substrate (5059): Damage to fetus possible.

Teratogenicity

No data available

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): TMB Substrate (5059): Inhalation – May cause respiratory irritation.
Repeated Exposure (GHS): No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

Synergistic Effects

No data available

Additional Information

Sensitization: Contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

TMB Substrate: Stomach – Irregularities – Based on human evidence (Hydrogen Peroxide)
Section 12 – Ecological Information

**Ecotoxicity**  No data available  **Mobility in Soil**  No data available

**Persistence / Degradability**  No data available  **PBT and vPvB Assessment**  No data available

**Bioaccumulation**  No data available  **PBT and vPvB Assessment**  No data available

**Other Adverse Effects**  An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

*Proclin 300 is very toxic to aquatic life with long lasting effects.*

Section 13 – Disposal Considerations

**Waste Disposal Instructions**
Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

**Disposal of Product and Contaminated Packaging**
Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

**U.S. Department of Transportation (DOT)**  This kit is not regulated for transport.

**International Air Transportation (IATA)**  This kit is not regulated for transport.

**International Maritime Dangerous Goods (IMDG)**  This kit is not regulated for transport.

Section 15 – Regulatory Information

**Regulatory Information**

**U.S. Federal Regulations**

**OSHA Hazards**
- Stop Solution (A9947), 20X Wash Solution (A9957), Complement Sample Diluent (A3670), and Hydrating Reagent (A3675): Irritant
- TMB Substrate (5059): Irritant, damage to fetus possible.

**SARA 302**
The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
- No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313**
The following chemicals are subject to reporting levels established by SARA Title III, Section 313:
- Hydrochloric Acid  CAS#: 7647-01-0  Revision Date: 1993-04-24  Acute Health Hazard
- Proclin 300  CAS#: 55965-84-9  Acute Health Hazard
- TMB Substrate (Proprietary Mixture)  CAS#: Not available  Acute Health Hazard, Chronic Health Hazard
State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Mixture for Proclin 300:</strong></td>
<td>5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td>55965-84-9</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>TMB Substrate (Proprietary Mixture)</td>
<td>--</td>
<td>No data available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**California Prop 65:** TMB Substrate (5059) – WARNING – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**Canadian – WHMIS Classification (Raw Material)**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>1310-73-2</td>
<td>E Corrosive - Corrosive to metal and skin.</td>
</tr>
<tr>
<td><strong>Mixture for Proclin 300:</strong></td>
<td>5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td>55965-84-9</td>
</tr>
<tr>
<td>TMB Substrate (Proprietary Mixture)</td>
<td>--</td>
<td>D2B Toxic material causing other toxic effects - Severe eye irritant</td>
</tr>
</tbody>
</table>

**Additional Regulatory Information**

**Safety, Health and Environmental regulations/legislation specific for the mixture:**


**Chemical Safety Assessment:**

Not completed for the components contained within this kit.

**TMB Substrate (5059):** The employer shall asses the working conditions and if there is any risk to the safety or health and effects on the pregnancy or breastfeeding of workers, take necessary measures to adjust the working conditions.

**NFPA Kit Classification:**

Health Hazard (blue): 2
Fire Hazard (red): 1
Reactivity Hazard(yellow): 0
Special Hazard (white): None
### Section 16 – Other Information

<table>
<thead>
<tr>
<th>PREPARED BY:</th>
<th>Quidel Corporation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12544 High Bluff Drive, Suite 200</td>
</tr>
<tr>
<td></td>
<td>San Diego, CA 92130</td>
</tr>
</tbody>
</table>

**SUPERCEDES:** May 23, 2017

**REVISIONS:** Section 7, updated specific use statement; Section 15, Removed HMIS kit classification

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, however arising, even if Quidel has been advised of the possibility of such damages.