Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

Material Safety Data Sheet

Section 1: Identification

Product Name:	OneStep FOB RapidCard InstaTest (**Fecal Occult Blood Rapid**)
Part Number:	13091-1-19
Manufactured by:	Diagnostic Automation/Cortez Diagnostics, Inc.
Street Address:	21250 Califa St. Suite 102 and 116,
City, State, Zip:	Woodland Hills, CA 91367 USA
Telephone Number:	818-591-3030
Fax Number:	818-591-8383

Section 2: Hazard(s) Identification

Emergency Overview-	NOT HAZARDOUS
Device:	Lead and other heavy metals-not used in/on device. Desiccant granules sealed within packet non-toxic but can be irritant.
Bottle(s):	1x Phosphate buffer solution (PBS) preserved with < 0.02% Sodium Azide. The product contains no substance which at their given concentration are considered to be hazardous to health according to Directive 67/548/EEC.

Section 3: Product Composition/Information on Ingredients

Diagnostic test strip(s) with/without plastic cassette packaged in foil pouch with desiccant packet. Kit also includes plastic bottle with wash buffer.

Section 4: First Aid Measures

Rinse eyes if contacted by desiccant granules or buffer solution. If ingested, contact a physician.

Section 5: Fire Fighting Measures

As appropriate to plastic and paper (water, carbon dioxide, dry chemical, foam).

Section 6: Accidental Release Measures

Not applicable to device. Spilled buffer should be wiped up directly and the area cleaned.

Section 7: Handling and Storage

Room temperature (59-86°F / 15-30°C) storage for product longevity-more extreme conditions do not present safety hazard.

Section 8: Exposure Controls/Personal Protection

Not applicable to device. Applicable PPE for use environment.

Section 9: Physical/Chemical Properties

Appearance:	Test strip or plastic cassette in foil pouch	Buffer in plastic bottle
Physical Properties:	Odorless, solid	Odorless, liquid
Other (boiling point, solubility, pH, etc.):	not applicable	

Section 10: Stability and Reactivity

Stability: Stable

Reactivity: No dangerous reactions known for device.
See insert or Certificate of Analysis for use of individual products.
Sodium Azide is at a concentration (< 0.02%) much lower than that which is potentially reactive with metals and other substances.

Hazardous Polymerization: will not occur.

Hazardous Decomposition Products and Incompatibility-not known.

Section 11: Toxicological Information

Route of exposure: skin contact, eye contact & inhalation: granules within desiccant packet nontoxic but can be irritant.

Section 12: Ecological Information

No applicable information.

Section 13: Disposal Consideration

Device itself may be disposed as solid waste. Devices tested with patient samples should be handled as potentially biohazardous materials in accordance with federal, state and local regulations. The amount of Sodium Azide in the wash buffer will not cause disposal problems.

Section 14: Transport Information

Proper Shipping Name: None

Kits and devices: not dangerous, not hazardous and not restricted to transport by IATA.

Section 15: Regulatory Information

Not restricted for safety reasons.

Section 16: Other Information

The above information is believed to be correct but is not intended to be all inclusive and shall be used only as a guide. Cortez Diagnostics, Inc. makes no warranty, express or implied, and assumes no liability for any damage resulting from the information contained above. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

ISO 13485
ISO 9001

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