

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Sofia RSV FIA (Catalog #: 20242 and 20260)

Recommended Use: The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients less than 19 years of age. A negative test is presumptive, and it is recommended these results be confirmed by virus culture or an FDA-cleared RSV molecular assay. This assay is for in vitro diagnostic use only.

Components: Kit is composed of individually pouched test cassettes, reagent tubes, reagent solution, sterile nasopharyngeal swabs, pink fixed volume pipettes (large), clear fixed volume pipettes (small), RSV positive control swab (swab is coated with non-infectious RSV antigen) and negative control swab (swab is coated with heat-inactivated, non-infectious Streptococcus C antigen).

Section 2 – Hazards Identification

2.1 Emergency Overview

Significant health effects are not anticipated from routine use of this kit when following Universal Precautions and general safety laboratory practices. None of the components listed within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives.

When working with this kit we always recommend that employees wear appropriate personal protective equipment (PPE), including gloves, a lab coat and eye protection, and follow good laboratory hygiene practices to avoid any and all accidental exposure to workplace materials. Universal Precautions should be followed when working with any potentially infectious material.

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Volume
SAFETY DATA SHEET (SDS) NOT REQUIRED FOR THIS TEST KIT					
There are no hazardous chemicals contained within the components in this kit at concentrations that are considered hazardous to personal health and/or the environment.					

Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

PREPARED BY: Quidel Corporation 10165 McKellar Court San Diego, CA 92121 858.552.1100	SUPERCEDES: 08/21/2013	REVISIONS: New branding and brand format.
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