

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Sofia Influenza A+B FIA (Catalog #: 20218, 20254, 20289)

Recommended Use: The Sofia Influenza A+B FIA employs immunofluorescence for detection of Influenza A and Influenza B viral nucleoprotein antigen in nasal swab, nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. This test is intended for professional and laboratory use only.

Components: Kit is composed of individually pouched test cassettes, reagent tubes, reagent solution, sterile nasal swabs, fixed volume pipettes, Influenza Type A and B positive control swab (swab is coated with non-infectious recombinant influenza A and influenza B antigens) and negative control swab (swab is coated with formalin-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 safe 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 it is recommended 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 this kit at concentrations that are considered hazardous to personal health and/or the environment.					
NOTE: Sodium azide (<0.02%) is used as a preservative in the Reagent Solution.					

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 (EHS Department)

SUPERCEDES: January 15, 2014

REVISIONS: Added part number 20289 to product name; added statement regarding sodium azide as a preservative in Section 3.

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