Sofia hCG FIA

Revision Date: November 1, 2013

Section 1 - Product and Company Identification

1.1 Manufacturer Information

Quidel Corporation Phone: 1.800.874.1517 Web: <u>quidel.com</u>

10165 McKellar Court Fax: 1.858.453.4338 E-mail: gehs@guidel.com

San Diego, CA 92121 Emergency (24-Hour): 1.866.519.4752

1.2 Product Information

Product Name: Sofia hCG FIA (Catalog #: 20229, 20266)

Recommended Use: The Sofia hCG FIA is an immunofluorescence-based lateral flow assay intended for the

qualitative detection of human Chorionic Gonadotropin (hCG) in urine specimens for the early

detection of pregnancy.

Components: Kit is composed of individually pouched test cassettes and fixed volume pipettes.

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. The Sofia hCG FIA kit is not 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 buffer 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 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 SUPERCEDES: July 15, 2013 REVISIONS: New branding and brand format

10165 McKellar Court San Diego, CA 92121

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, howsoever arising, even if Quidel has been advised of the possibility of such damages.

0188RA0713D-1 (11/13)