

Language	en
Revision No.:	26
Date:	2022-05-16

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

1.1.1 Trade name/designation	1.1.2 Code
CONJ Conjugate	Kit components: LIAISON® Borrelia IgM II REF 310010
CONJ Conjugate	Kit components: LIAISON® Borrelia IgM Quant REF 310020
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate	Kit components: LIAISON® HBsAg REF 310100
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control HBsAg REF 310101
Anti-HBs Anti-HBs antibodies DIL/SPE Specimen diluent	Kit components: HBsAg Confirmatory test REF 310110
CAL 1 Calibrator 1 CAL 2 Calibrator 2	Kit components: LIAISON® Anti-HBc REF 310130
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control Anti-HBc REF 310131
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate	Kit components: LIAISON® HBeAg REF 310150
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control HBeAg REF 310151
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate Ag Antigen (HBeAg)	Kit components: LIAISON® Anti-HBe REF 310160
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control Anti-HBe REF 310161
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate	Kit components: LIAISON® Anti-HAV REF 310170
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control Anti-HAV REF 310171

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1.1.1 Trade name/designation	1.1.2 Code
CONJ Conjugate	Kit components: LIAISON® HAV IgM REF 310180
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control HAV IgM REF 310181
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate	Kit components: LIAISON® Anti-HAV REF 310200
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control Anti-HAV REF 310201
CONJ Conjugate	Kit components: LIAISON® HAV IgM REF 310210
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control HAV IgM REF 310211
CAL 1 Calibrator 1 CAL 2 Calibrator 2	Kit components: LIAISON® Anti-HBs II REF 310220
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® Control Anti-HBs II REF 310221
CAL 1 Calibrator 1 CAL 2 Calibrator 2 DIL SPE Specimen diluent	Kit components: LIAISON® Anti-HBs II Plus REF 310230
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control HCV Ab REF 310241
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control HCV Ab II REF 310246
CAL Calibrator CONJ A Conjugate A CONJ B Conjugate B	Kit components: LIAISON® XL MUREX rec HTLV-I/II REF 310270
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control recHTLV-I/II REF 310271
CONJ Conjugate DIL SPE Specimen diluent	Kit components: LIAISON® XL MUREX Chagas REF 310280

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<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® XL MUREX Control Chagas REF 310281				
CONTROL -	Negative control								
CONTROL +	Positive control								
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® ANA Screen REF 310300						
CONJ	Conjugate								
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® dsDNA REF 310310						
CONJ	Conjugate								
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® ENA Screen REF 310330						
CONJ	Conjugate								
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Direct Renin REF 310350						
CONJ	Conjugate								
<table border="1"> <tr> <td>SORB</td> <td>Magnetic Particles</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	SORB	Magnetic Particles	CONJ	Conjugate	Kit components: LIAISON® Cardiolipin IgG REF 310370				
SORB	Magnetic Particles								
CONJ	Conjugate								
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control Cardiolipin IgG REF 310371				
CONTROL -	Negative control								
CONTROL +	Positive control								
<table border="1"> <tr> <td>SORB</td> <td>Magnetic Particles</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	SORB	Magnetic Particles	CONJ	Conjugate	Kit components: LIAISON® Cardiolipin IgM REF 310380				
SORB	Magnetic Particles								
CONJ	Conjugate								
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control Cardiolipin IgM REF 310381				
CONTROL -	Negative control								
CONTROL +	Positive control								
<table border="1"> <tr> <td>CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td>CAL 2</td> <td>Calibrator 2</td> </tr> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CAL 1	Calibrator 1	CAL 2	Calibrator 2	DIL SPE	Specimen diluent	CONJ	Conjugate	Kit components: LIAISON® DHEA-S REF 310430
CAL 1	Calibrator 1								
CAL 2	Calibrator 2								
DIL SPE	Specimen diluent								
CONJ	Conjugate								
<table border="1"> <tr> <td>CONTROL 1</td> <td>Control 1</td> </tr> <tr> <td>CONTROL 2</td> <td>Control 2</td> </tr> </table>	CONTROL 1	Control 1	CONTROL 2	Control 2	Kit components: LIAISON® Control DHEA-S REF 310431				
CONTROL 1	Control 1								
CONTROL 2	Control 2								
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Rubella IgG REF 310460						
CONJ	Conjugate								
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> <tr> <td>CONTROL H +</td> <td>Low positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	CONTROL H +	Low positive control	Kit components: LIAISON® Rubella IgG Tri-Controls REF 310461		
CONTROL -	Negative control								
CONTROL +	Positive control								
CONTROL H +	Low positive control								
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CONJ	Conjugate								

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CONJ Conjugate	Kit components: LIAISON® Treponema Assay REF 310480
CONJ Conjugate	Kit components: LIAISON® VZV IgG REF 310495
CONTROL - CONTROL + Negative control Positive control	Kit components: LIAISON® Control VZV IgG REF 310496
CONJ Conjugate	Kit components: LIAISON® EBV IgM REF 310500
CONTROL - CONTROL + Negative control Positive control	Kit components: LIAISON® EBV IgM Serum Control Set REF 310502
CONJ Conjugate	Kit components: LIAISON® VCA IgG REF 310510
CONJ Conjugate	Kit components: LIAISON® EBNA IgG REF 310520
CONJ Conjugate	Kit components: LIAISON® EA IgG REF 310540
CONJ Conjugate	Kit components: LIAISON® Toxo IgG II REF 310705
CONTROL - CONTROL + Negative control Positive control	Kit components: LIAISON® Control Toxo IgG II REF 310706
CONJ Conjugate Ag Antigen	Kit components: LIAISON® Toxo IgM REF 310710
CONJ Conjugate Ag Antigen	Kit components: LIAISON® Toxo IgM II REF 310715
CONTROL - CONTROL + Negative control Positive control	Kit components: LIAISON® Control Toxo IgM II REF 310716
CONJ Conjugate	Kit components: LIAISON® Rubella IgG REF 310720
CONJ Conjugate	Kit components: LIAISON® Rubella IgM REF 310730

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CONTROL -	Negative control				
CONTROL +	Positive control				
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CONJ	Conjugate				
<table border="1"> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	DIL SPE	Specimen diluent	CONJ	Conjugate	Kit components: LIAISON® CMV IgG II REF 310745
DIL SPE	Specimen diluent				
CONJ	Conjugate				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® CMV IgM REF 310750		
CONJ	Conjugate				
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® CMV IgM Serum Control Set REF 310752
CONTROL -	Negative control				
CONTROL +	Positive control				
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CONJ	Conjugate				
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> </table>	CONTROL -	Negative control	Kit components: LIAISON® Control CMV IgM II REF 310756		
CONTROL -	Negative control				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> <tr> <td>BUF B</td> <td>Buffer B</td> </tr> </table>	CONJ	Conjugate	BUF B	Buffer B	Kit components: LIAISON® CMV IgG Avidity II REF 310765
CONJ	Conjugate				
BUF B	Buffer B				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Toxo IgG II REF 310780		
CONJ	Conjugate				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® XL Toxo IgG Avidity REF 310795		
CONJ	Conjugate				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® HSV-1/2 IgG REF 310800		
CONJ	Conjugate				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® HSV-2 IgG REF 310810		
CONJ	Conjugate				
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CONJ	Conjugate				
<table border="1"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Treponema Screen REF 310840		
CONJ	Conjugate				
<table border="1"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control Treponema Screen REF 310841
CONTROL -	Negative control				
CONTROL +	Positive control				

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<input type="checkbox"/> CONTROL -	Negative control								
<input type="checkbox"/> CONTROL +	Positive control								
<input type="checkbox"/> CONJ Conjugate	Kit components: LIAISON® VZV IgG <input type="checkbox"/> REF 310850								
<table border="0"> <tr> <td><input type="checkbox"/> CONTROL -</td> <td>Negative control</td> </tr> <tr> <td><input type="checkbox"/> CONTROL +</td> <td>Positive control</td> </tr> </table>	<input type="checkbox"/> CONTROL -	Negative control	<input type="checkbox"/> CONTROL +	Positive control	Kit components: LIAISON® Control VZV IgG <input type="checkbox"/> REF 310851				
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<input type="checkbox"/> CONTROL +	Positive control								
<input type="checkbox"/> CONJ Conjugate	Kit components: LIAISON® VZV IgM <input type="checkbox"/> REF 310860								
<table border="0"> <tr> <td><input type="checkbox"/> CONTROL -</td> <td>Negative control</td> </tr> <tr> <td><input type="checkbox"/> CONTROL +</td> <td>Positive control</td> </tr> </table>	<input type="checkbox"/> CONTROL -	Negative control	<input type="checkbox"/> CONTROL +	Positive control	Kit components: LIAISON® Control VZV IgM <input type="checkbox"/> REF 310861				
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<input type="checkbox"/> CONTROL +	Positive control								
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<input type="checkbox"/> BUF W Assay Buffer W	Kit components: LIAISON® QuantiFERON®-TB Gold Plus <input type="checkbox"/> REF 311010								
<input type="checkbox"/> BUF W Assay Buffer W	Kit components: LIAISON® QuantiFERON®-TB Gold Plus <input type="checkbox"/> REF 311020								
<table border="0"> <tr> <td><input type="checkbox"/> CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td><input type="checkbox"/> CAL 2</td> <td>Calibrator 2</td> </tr> </table>	<input type="checkbox"/> CAL 1	Calibrator 1	<input type="checkbox"/> CAL 2	Calibrator 2	Kit components: LIAISON® XL MUREX Anti-HBs <input type="checkbox"/> REF 311220				
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<input type="checkbox"/> CAL 2	Calibrator 2								
<table border="0"> <tr> <td><input type="checkbox"/> CONTROL -</td> <td>Negative control</td> </tr> <tr> <td><input type="checkbox"/> CONTROL +</td> <td>Positive control</td> </tr> </table>	<input type="checkbox"/> CONTROL -	Negative control	<input type="checkbox"/> CONTROL +	Positive control	Kit components: LIAISON® XL MUREX Control Anti-HBs <input type="checkbox"/> REF 311221				
<input type="checkbox"/> CONTROL -	Negative control								
<input type="checkbox"/> CONTROL +	Positive control								
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<input type="checkbox"/> CAL 1	Calibrator 1								
<input type="checkbox"/> CAL 2	Calibrator 2								
<input type="checkbox"/> DIL SPE	Specimen diluent								
<input type="checkbox"/> CONJ Conjugate	Kit components: LIAISON® XL MUREX Anti-HDV <input type="checkbox"/> REF 311260								
<table border="0"> <tr> <td><input type="checkbox"/> CONTROL -</td> <td>Negative control</td> </tr> <tr> <td><input type="checkbox"/> CONTROL +</td> <td>Positive control</td> </tr> </table>	<input type="checkbox"/> CONTROL -	Negative control	<input type="checkbox"/> CONTROL +	Positive control	Kit components: LIAISON® XL MUREX Control Anti-HDV <input type="checkbox"/> REF 311261				
<input type="checkbox"/> CONTROL -	Negative control								
<input type="checkbox"/> CONTROL +	Positive control								
<table border="0"> <tr> <td><input type="checkbox"/> CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td><input type="checkbox"/> CAL 2</td> <td>Calibrator 2</td> </tr> <tr> <td><input type="checkbox"/> DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td><input type="checkbox"/> CONJ</td> <td>Conjugate</td> </tr> </table>	<input type="checkbox"/> CAL 1	Calibrator 1	<input type="checkbox"/> CAL 2	Calibrator 2	<input type="checkbox"/> DIL SPE	Specimen diluent	<input type="checkbox"/> CONJ	Conjugate	Kit components: LIAISON® SARS-CoV-2 S1/S2 IgG <input type="checkbox"/> REF 311450
<input type="checkbox"/> CAL 1	Calibrator 1								
<input type="checkbox"/> CAL 2	Calibrator 2								
<input type="checkbox"/> DIL SPE	Specimen diluent								
<input type="checkbox"/> CONJ	Conjugate								
<table border="0"> <tr> <td><input type="checkbox"/> CONTROL -</td> <td>Negative control</td> </tr> <tr> <td><input type="checkbox"/> CONTROL +</td> <td>Positive control</td> </tr> </table>	<input type="checkbox"/> CONTROL -	Negative control	<input type="checkbox"/> CONTROL +	Positive control	Kit components: LIAISON® Control SARS-CoV-2 S1/S2 IgG <input type="checkbox"/> REF 311451				
<input type="checkbox"/> CONTROL -	Negative control								
<input type="checkbox"/> CONTROL +	Positive control								

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<table border="0"> <tr> <td>CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td>CAL 2</td> <td>Calibrator 2</td> </tr> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CAL 1	Calibrator 1	CAL 2	Calibrator 2	DIL SPE	Specimen diluent	CONJ	Conjugate	Kit components: LIAISON® SARS-CoV-2 S1/S2 IgG REF 311460		
CAL 1	Calibrator 1										
CAL 2	Calibrator 2										
DIL SPE	Specimen diluent										
CONJ	Conjugate										
<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control SARS-CoV-2 S1/S2 IgG REF 311461						
CONTROL -	Negative control										
CONTROL +	Positive control										
<table border="0"> <tr> <td>CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td>CAL 2</td> <td>Calibrator 2</td> </tr> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> <tr> <td>BUF</td> <td>Assay Buffer</td> </tr> </table>	CAL 1	Calibrator 1	CAL 2	Calibrator 2	DIL SPE	Specimen diluent	CONJ	Conjugate	BUF	Assay Buffer	Kit components: LIAISON® SARS-CoV-2 IgM REF 311470
CAL 1	Calibrator 1										
CAL 2	Calibrator 2										
DIL SPE	Specimen diluent										
CONJ	Conjugate										
BUF	Assay Buffer										
<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control SARS-CoV-2 IgM REF 311471						
CONTROL -	Negative control										
CONTROL +	Positive control										
<table border="0"> <tr> <td>CAL 1</td> <td>Calibrator 1</td> </tr> <tr> <td>CAL 2</td> <td>Calibrator 2</td> </tr> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> <tr> <td>BUF</td> <td>Assay Buffer</td> </tr> </table>	CAL 1	Calibrator 1	CAL 2	Calibrator 2	DIL SPE	Specimen diluent	CONJ	Conjugate	BUF	Assay Buffer	Kit components: LIAISON® SARS-CoV-2 IgM REF 311480
CAL 1	Calibrator 1										
CAL 2	Calibrator 2										
DIL SPE	Specimen diluent										
CONJ	Conjugate										
BUF	Assay Buffer										
<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control SARS-CoV-2 IgM REF 311481						
CONTROL -	Negative control										
CONTROL +	Positive control										
<table border="0"> <tr> <td>DIL SPE</td> <td>Specimen diluent</td> </tr> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	DIL SPE	Specimen diluent	CONJ	Conjugate	Kit components: LIAISON® Rubella IgG II REF 317260						
DIL SPE	Specimen diluent										
CONJ	Conjugate										
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CONTROL -	Negative control										
CONTROL +	Positive control										
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CONJ	Conjugate										
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DIL	Diluent										
<table border="0"> <tr> <td>DIL</td> <td>Diluent</td> </tr> </table>	DIL	Diluent	Kit components: LIAISON® BRAHMS PCT® II GEN Samples diluent REF 318043								
DIL	Diluent										
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CONJ	Conjugate										
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DIL	Diluent										

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DIL Diluent	Kit components: LIAISON® BRAHMS PCT® II GEN Verifiers REF 318092
CAL 1 Calibrator 1 CAL 2 Calibrator 2	Kit components: LIAISON® MUREX Anti-HBc REF 318130
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® MUREX Control Anti-HBc REF 318131
CAL 1 Calibrator 1 CAL 2 Calibrator 2 BUF E Buffer E CONJ Conjugate	Kit components: LIAISON® XL MUREX HBc IgM REF 318140
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control HBc IgM REF 318141
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate	Kit components: LIAISON® XL MUREX HBeAg REF 318150
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control HBeAg REF 318151
CAL 1 Calibrator 1 CAL 2 Calibrator 2 CONJ Conjugate Ag Antigen (HBeAg)	Kit components: LIAISON® XL MUREX Anti-HBe REF 318160
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control Anti-HBe REF 318161
CAL 1 Calibrator 1 CAL 2 Calibrator 2	Kit components: LIAISON® XL MUREX Anti-HBs REF 318220
CONTROL - Negative control CONTROL + Positive control	Kit components: LIAISON® XL MUREX Control Anti-HBs REF 318221
CONTROL A Control A CONTROL B Control B CONTROL C Control C CONTROL D Control D	Kit components: LIAISON® XL MUREX Anti-HBs Verifiers REF 318223
CONJ Conjugate	Kit components: LIAISON® Measles IgG REF 318810

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<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control Measles IgG REF 318811
CONTROL -	Negative control				
CONTROL +	Positive control				
<table border="0"> <tr> <td>CAL1</td> <td>Calibrator 1</td> </tr> </table>	CAL1	Calibrator 1	Kit components: LIAISON® Measles IgM REF 318820		
CAL1	Calibrator 1				
<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> </table>	CONTROL -	Negative control	Kit components: LIAISON® Control Measles IgM REF 318821		
CONTROL -	Negative control				
<table border="0"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Mumps IgG REF 318840		
CONJ	Conjugate				
<table border="0"> <tr> <td>CONTROL -</td> <td>Negative control</td> </tr> <tr> <td>CONTROL +</td> <td>Positive control</td> </tr> </table>	CONTROL -	Negative control	CONTROL +	Positive control	Kit components: LIAISON® Control Mumps IgG REF 318841
CONTROL -	Negative control				
CONTROL +	Positive control				
<table border="0"> <tr> <td>CONJ</td> <td>Conjugate</td> </tr> </table>	CONJ	Conjugate	Kit components: LIAISON® Bordetella pertussis Toxin IgA REF 318860		
CONJ	Conjugate				
<table border="0"> <tr> <td>CONTROL NR</td> <td>Non-reactive control</td> </tr> </table>	CONTROL NR	Non-reactive control	Kit components: LIAISON® Control Bordetella pertussis Toxin IgA REF 318861		
CONTROL NR	Non-reactive control				


The information included in this safety data sheet exclusively refers to the components mentioned in point 1.1.1

Chemical denomination

Solution containing a reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1)

1.2 Relevant identified uses of the substance or mixture and uses advised against

laboratory reagents for in vitro diagnostics.

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1.3 Details of the supplier of the safety data sheet

DiaSorin S.p.A.
 Via Crescentino s.n.c
 13040 SALUGGIA (VC) - ITALY
 Tel.+39.0161.4871
www.diasorin.it

e-mail: msds@Diasorin.it

USA Distributor:

DiaSorin Inc.
 1951 Northwestern Avenue
 Stillwater, MN 55082 USA
 Tel: 651-439-9710

1.4 Emergency telephone number

European emergency number: 112

United Kingdom of Great Britain and Northern Ireland

National Poisons Information Service (Birmingham Unit)
 City Hospital
 Dudley Rd
 Birmingham

Telephone number: +44 121 507 4123
Emergency telephone number: 844 892 0111
Fax: +44 121 507 55 88
E-mail: mail@npis.org

National Poisons Information Service Edinburgh
 Scottish Poisons Information Bureau
 Royal Infirmary
 51 Little France Crescent
 Edinburgh

Telephone number: +44 131 242 1383
Emergency telephone number: 844 892 0111
Fax: +44 131 242 13 87
E-mail: spib@luht.scot.nhs.uk

Emergency number: 999

Ireland

Poisons Information Centre of Ireland
 Beaumont Hospital
 PO Box 1297
 Dublin

Telephone number: +353 1 809 25 66
Emergency telephone number:
 +353 1 837 9964 (medical professionals)
 +353 1 809 2166 (public)
Fax: +353 1 836 84 76
E-mail: npicdublin@beaumont.ie

Emergency number: 999

The Netherlands

National Poisons Information Centre, The Netherlands
 University Medical Centre Utrecht
 Postbus 85500
 Utrecht

Telephone number: +31 88 755 85 61
Emergency telephone number: +31 30 274 88 88
Fax: +31 30 254 15 11
E-mail: nvic@umcutrecht.nl

Malta


Mater Dei Hospital
 Msida MSD 2090
 MALTA

Telephone number: 2545-0000
Fax: 2545 4154
E-mail: mdh@gov.mt

Australia

NSW Poisons Information Centre
 Childrens Hospital Westmead
 Hawkesbury Road
 Westmead

Telephone number: +61 2 9845 3969
Emergency telephone number: 131126 (national calls)
Fax: +61 2 9845 3597
E-mail: www.poisonsinfo.nsw.gov.au

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South Africa

Tygerberg Poison Information Centre
 Division of Pharmacology, Department of Medicine
 Faculty of Health Sciences
 Tygerberg Campus
 Stellenbosch University
 Tygerberg

Telephone number: +27 21 938 6084
Emergency telephone number: +27 (0)861 555 777
Fax: +27 21 938 91 22
E-mail: toxicology@sun.ac.za

Canada

IWK Regional Poison Center
 5850/5980 University Avenue
 Halifax

Telephone number: +1 902 470 81320
Emergency telephone number: +1 902 470 8161 / 1 800 565 8161
Fax: +1 902 470 7213
E-mail: poison.center@iwk.nshealth.ca

Ontario Poison Centre
 Hospital for Sick Children
 555 University Avenue
 Toronto

Telephone number: +1 416 813 6437
Emergency telephone number: +1 416 813 5900 or 1 800 268 9017
Fax: +1 416 813 7489
E-mail: poison.information@sickkids.ca

USA

DiaSorin Inc.

National Poison Control Centers:

Telephone number: 651-439-9710 (8:00a.m. – 4:30p.m. CST)
Emergency telephone number: +1 800 222 1222


SECTION 2 HAZARDS IDENTIFICATION

Hazard classification and hazard statements are specific for products sold in the European market, since they have been defined taking in account the specific concentration limits reported for CAS 55965-84-9 in Part 3 - table 3.1 of Annex VI to Regulation (EC) No 1272/2008.

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008
Skin sens. 1 H317


2.2 Label elements

REGULATION (EC) No 1272/2008	
SIGNAL WORD:	Warning
SYMBOLS / PICTOGRAMS:	 GHS07 Exclamation mark
HAZARD STATEMENTS:	H317 May cause an allergic skin reaction.
PRECAUTIONARY STATEMENTS:	P261 Avoid breathing dust/fume/gas/mist/vaporous/spray. P280 Wear protective gloves/protective clothing/eye protection/face protection. P363 Wash contaminated clothing before reuse

Contains: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1).

2.3 Other hazards

Potential biological hazard: contains biological materials of human/animal origin.

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SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

N.A.

3.2 Mixtures

Contains:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

CAS No.	CE No.	Index No.	Concentration	Classification Reg. 1272/2008 (pure substance)
55965-84-9	--	613-167-00-5	0.006 % ≤ C ≤ 0.012 %	Acute Tox. 3 H331 Acute Tox. 3 H311 Acute Tox. 3 H301 Skin Corr. 1B H314 Skin Sens. 1 H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Refer to §16 for complete text of hazard statements and class.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

Seek medical advice for first aid; protect first aid providers; wear suitable hand and eye protection and, if necessary, breathing protection.

Inhalation: Take the person outdoors to fresh air and seek medical advice. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: If on skin: disinfect and wash with plenty of soap and water. Remove contaminated clothing. Seek medical advice.

Eye contact: Rinse thoroughly with water or suitable eyewash. Seek medical advice.

Ingestion: Rinse mouth. Do not induce vomiting. Seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Seek medical advice as soon as possible.

SECTION 5 FIREFIGHTING MEASURES

5.1 Extinguishing media

Use suitable extinguishing media, such as: carbon dioxide, foams, sprayed water, sand or aggregates.

5.2 Special hazards arising from the substance or mixture


Non-combustible preparation. Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

Wear suitable protective clothing, including helmet and mask with self-contained breathing apparatus, CE certified according with Directive 89/686/EEC or NIOSH approved (USA).

Remove containers from the area of the fire if it is possible to do so without incurring risks.

Prevent fire-fighting water from entering surface water or groundwater. Collect in containers suitable for disposal.

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SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Free the contaminated area of non-emergency personnel.

Let fresh air enter contaminated area.

Avoid coming into contact with the substance and handling damaged containers without wearing suitable protective clothing and personal protection equipment for the face, hands and air-ways, CE certified according with Directive 89/686/EEC or NIOSH approved (USA).

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Cover spillage with inert absorbent material.

Recover spilled material by mechanical means and collect in clean and suitably labelled containers.

Thoroughly wash and disinfect contaminated surfaces.

6.4 Reference to other sections

Dispose of recovered material as waste (see section 13); use personal protection equipment as indicated in section 8.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with eyes, skin or clothing. Use in a suitably ventilated room. Do not eat, drink or smoke during use. Do not pipette by mouth. Wear lab coats, safety goggles and disposable gloves. Avoid splashing or forming an aerosol. Wash hands carefully on completion of operations.

7.2 Conditions for safe storage, including any incompatibilities

Store the preparation at 2-8°C hermetically sealed and away from the light. Keep away from foodstuffs, drinks and animal feed. Protect containers against damage.

7.3 Specific end uses

The mixtures are intended specifically for in vitro use, for the examination of samples of human origin. Handle in accordance with good laboratory practice (GLP), while also considering the risks deriving from the materials under analysis.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Eye/face protection: wear safety goggles or visor CE-certified in accordance with Directive 89/686/EEC or (for USA) meeting at a minimum ANSI standard Z87.1; do not use contact lenses.

Hand protection: wear CE-certified protective gloves in accordance with Directive 89/686/EEC suitable for handling chemical and biological agents.

Body protection: select any protection equipment according to the quantities of hazardous materials in the work place.

Breathing protection: avoid inhaling aerosol. If necessary use suitable fume hoods and/or full face-masks with type ABEKP combined filters (EN 14387), CE certified.

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SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- (a) Appearance: liquid
- (b) Odour: N.A.
- (c) Odour threshold: N.A.
- (d) pH: 6 to 8
- (e) Melting point/freezing point: no information available
- (f) Initial boiling point and boiling range: no information available
- (g) Flash point: no information available
- (h) Evaporation rate: no information available
- (i) Flammability (solid, gas): N.A.
- (j) Upper/lower flammability or explosive limits: N.A.
- (k) Vapour pressure: no information available
- (l) Vapour density: no information available
- (m) Relative density: no information available
- (n) Solubility(ies): no information available
- (o) Partition coefficient: n-octanol/water: no information available
- (p) Auto-ignition temperature: no information available
- (q) Decomposition temperature: no information available
- (r) Viscosity: no information available
- (s) Explosive properties: N.A.
- (t) Oxidising properties: no information available

9.2 Other information

Not available.

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical stability

Stable in recommended storage conditions.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid


No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

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SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

No product information available;

information on hazardous components: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Acute toxicity by mouth, skin and inhalation

LD-50 (oral), rat: 60 mg/kg (active isothiazol)

LD-50 (dermal), rabbit: 80 mg/kg (active isothiazols)

LC-50 4-hour (inhalation), rat: 330 mg/m³ (active isothiazols)

In humans, solutions containing more than 0.5% (5000 ppm) active isothiazols cause severe skin irritation and may be corrosive to the mucous membranes and cornea.

Corrosion, irritation and sensitization

The substance has manifested sensitizing effects.

In humans, solutions containing more than 0.5% (5000 ppm) active isothiazols cause severe skin irritation and may be corrosive to the mucous membranes and cornea.

The application of single doses of 0.5 ml of an aqueous solution (with active isothiazols at 560, 2800 and 5600 ppm) to the skin of rabbits, causes after 24 hours, severe skin damage at 5600 ppm and moderate damage at 2800 ppm; no effects are observed at 560 ppm.

Long-term toxicity (sub-acute, sub-chronic, chronic)


In a study conducted on rats, the inhalation of concentrations of active isothiazols of 0, 0.027, 0.23 and 0.89 mg/m³ in aerosol form, for 6 hours/day for 5 days/week for 13 weeks, caused, at the high doses, reduced body growth in both sexes, reduced blood proteins in females and reduced spleen weight in males. Histopathological examination revealed mild rhinitis at the dose of 0.23 mg/m³.

Carcinogenicity, Mutagenicity and Reproductive Toxicity (fertility and development)

In a study of carcinogenicity conducted on mice by means of cutaneous administration of substance, the substance did not manifest cutaneous and/or systemic carcinogenic potential.

Assays of mutagenicity showed the substance to be cytotoxic and directly mutagenic in vitro, in two species of bacteria and one mammalian cell line. In studies in vitro on mammalian cells it was not observed to cause damage to DNA, and in vivo, no formation of bonds with DNA was observed.

The substance manifested no reproductive toxicity.

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SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

Mixture: no information available.

Information on hazardous components reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); short-term effects:

Parameter	Animal species	Time of exposure	Data
LC50	Fish	96 hours	0.19 mg/l
EC50	Crustaceans	48 hours	0.16 mg/l

long-term effects: no information available

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

If spilled, may enter ground.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of contents/container in accordance with local/regional/national/international regulation in force. Use a dedicated company for dangerous waste disposal. Send for disposal as dangerous waste. Recommended disposal method: incineration. Normative references: Directives 94/62/EC, 2008/98/EC, Commission Decision 2000/532/EC.

SECTION 14 TRANSPORT INFORMATION

The mixture is not to be considered hazardous within the meaning of the provisions in force governing the transport of hazardous materials by road (ADR), rail (RID), sea (IMDG code) and air (ICAO, IATA); transport at 2-8°C.

14.1 UN number: N.A.

14.2 UN proper shipping name: N.A.


14.3 Transport hazard class(es): N.A.

14.4 Packing group: N.A.

14.5 Environmental hazards: N.A.

14.6 Special precautions for user: N.A.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: N.A.

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SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU	Restriction pursuant to Annex XVII to EC Regulation 1907/2006	Point 3		
	Seveso category	none		
	Candidate List (art. 59 Regulation 1907/2006)	NA		
	authorization (Annex XIV REACH)	NA		
	Water Hazard Class (Germany):	WGK 1		
UNITED STATES	Product components listed in Section 1.1 are classified in accordance with OSHA Hazard Communication Standard, 29 CFR 1910.1200, and individual US state Right-to-Know laws.			
	CAA:	N – Does not contain any hazardous air pollutants (HAPs) or Class 1 Ozone depletors.		
	CWA:	N		
	CERCLA:	N		
	SARA 302:	N		
	SARA 313:	N		
	TSCA:	Isothiazole compounds		
	CA Prop 65:	N		
Canada	DSL:	Isothiazole compounds		
	NDSL:	N		
Rotterdam Convention - annex III		NA		
Stockholm Convention		NA		
NFPA	Health: 1	Flammability: 0	Reactivity: 0	

15.2 Chemical safety assessment

No chemical safety assessment has been produced for the mixture and the substances contained therein.

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SECTION 16 OTHER INFORMATION

Hazard statements and class

Acute Tox.: Acute toxicity
 Skin Corr.: Skin corrosion
 Skin Sens.: Skin sensitization
 Aquatic Acute: Hazardous to the aquatic environment, acute toxicity
 Aquatic Chronic: Hazardous to the aquatic environment, chronic toxicity
 H331 Toxic if inhaled
 H311 Toxic in contact with skin
 H301 Toxic if swallowed
 H314 Causes severe skin burns and eye damage
 H317 May cause an allergic skin reaction
 H400 Very toxic to aquatic life
 H410 Very toxic to aquatic life with long-lasting effects

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. The Merck Index. - 10th Edition
4. Handling Chemical Safety
5. CDC - NIOSH website – Guide to Chemical Hazards
6. INRS - Fiche Toxicologique (toxicological sheet)
7. Patty - Industrial Hygiene and Toxicology
8. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
9. ECHA website
10. US OSHA 29 CFR 1910.1200
11. eChemPortal website
12. IARC website – Evaluation of carcinogenic risks to humans
13. Health Canada website
14. Canada Labour Health and Safety website
15. CCOHS website
16. World Health Organization - Laboratory biosafety manual, 3rd ed.
17. OECD – Principles of good laboratory practice

Further information

All information is correct, to the best of our knowledge, on the date of issue of the data sheet. It is provided for information purposes only, however, and does not constitute a guarantee.

Procedures for use: see instructions in the package. Do not use the product for any purpose other than that for which it is intended.

Judgments as to the suitability of information herein for the purchaser's purposes are necessarily the purchaser's responsibility. Although reasonable care has been taken in the preparation of such information, the company extends no warranties, makes no representations and assumes no responsibility as to accuracy or suitability of such information for application to purchaser's intended purposes and accepts no responsibility for any injury, loss or damage deriving from improper use of the product.

The product is employed under its users' control and it is their responsibility to comply with the correct operating procedures indicated, as well as to observe proper laboratory hygiene.

Nature of changes with respect to previous edition:

Product codes added in § 1.1	-
Product codes deleted from § 1.1	318700, 318830, 318850, 318851
Other changes	-