



## Specification of Final Product

### Safely Pregnancy

Criteria	Technical specification																																																
Analytical Sensitivity (Limit of detection)	<b>25 mIU/mL of hCG</b>																																																
Analytical specification	<p>Cross-reactivity</p> <p><b>Safely Pregnancy did not showed cross-reactivity with LH, FSH, TSH hormones</b></p> <table border="1"> <thead> <tr> <th>Homologous hormones</th> <th>Source</th> <th>Code No.</th> <th>Concentration tested</th> </tr> </thead> <tbody> <tr> <td>LH</td> <td>NIBSC</td> <td>2<sup>nd</sup> IS (80/552)</td> <td>500mIU/mL</td> </tr> <tr> <td>FSH</td> <td>NIBSC</td> <td>1<sup>st</sup> IS (92/512)</td> <td>1000mIU/mL</td> </tr> <tr> <td>TSH</td> <td>NIBSC</td> <td>1<sup>st</sup> IS (03/192)</td> <td>1000mIU/mL</td> </tr> </tbody> </table> <p>Interference</p> <p><b>13 interfering substances tested did not affect the performance of Safely Pregnancy</b></p> <table border="1"> <thead> <tr> <th>Analytes</th> <th>Concentration tested</th> <th>Analytes</th> <th>Concentration tested</th> </tr> </thead> <tbody> <tr> <td>Amoxicillin</td> <td>20 mg/dL</td> <td>Glucose</td> <td>2000 mg/dL</td> </tr> <tr> <td>Ampicillin</td> <td>20 mg/dL</td> <td>Hemoglobin</td> <td>10 mg/dL</td> </tr> <tr> <td>Ascorbic acid</td> <td>20 mg/dL</td> <td>Human Albumin</td> <td>20 mg/dL</td> </tr> <tr> <td>Bilirubin</td> <td>20 mg/dL</td> <td>Human IgG</td> <td>10 mg/dL</td> </tr> <tr> <td>Caffeine</td> <td>20 mg/dL</td> <td>Oxalic acid</td> <td>10 mg/dL</td> </tr> <tr> <td>Cyanocobalamine</td> <td>1 mg/dL</td> <td>Sodium Chloride</td> <td>10 mg/dL</td> </tr> <tr> <td>Ethanol</td> <td>10 mg/dL</td> <td></td> <td></td> </tr> </tbody> </table>	Homologous hormones	Source	Code No.	Concentration tested	LH	NIBSC	2 <sup>nd</sup> IS (80/552)	500mIU/mL	FSH	NIBSC	1 <sup>st</sup> IS (92/512)	1000mIU/mL	TSH	NIBSC	1 <sup>st</sup> IS (03/192)	1000mIU/mL	Analytes	Concentration tested	Analytes	Concentration tested	Amoxicillin	20 mg/dL	Glucose	2000 mg/dL	Ampicillin	20 mg/dL	Hemoglobin	10 mg/dL	Ascorbic acid	20 mg/dL	Human Albumin	20 mg/dL	Bilirubin	20 mg/dL	Human IgG	10 mg/dL	Caffeine	20 mg/dL	Oxalic acid	10 mg/dL	Cyanocobalamine	1 mg/dL	Sodium Chloride	10 mg/dL	Ethanol	10 mg/dL		
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Precision	<b>100%</b>																																																
Reading time	5 minutes																																																

QMR:

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Park, Hye Lim

Date:

*Handwritten date: 2021/12/16*