

ANALYSIS CERTIFICATE

Collagen - #AG005K

Lot : F1601325

QC Release: 2017-01-17

Expiration date : 2019-06-21

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
Collagen reagent	3 vials	30	F1601325	F1601325	2019-06-24
Collagen diluent	3 vials	30	F1601325	F1601325	2019-06-21

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Analytical data	Specifications												
<p>a. Intra-lot homogeneity collagen reagent:</p> <p style="text-align: center;">N = 15 vials</p> <p style="text-align: center;">CV (%AgregMax at 2µg/ml) = 3,8 %</p> <p style="text-align: center;">Aspect: in compliance / not in compliance</p>	<p>N ≥ 4</p> <p>CV ≤ 10%</p> <p>Transparent, slightly white</p>												
<p>b. Intra-lot homogeneity collagen diluent:</p> <p style="text-align: center;">N = 15 vials</p> <p style="text-align: center;">Volume = >12 mL</p> <p style="text-align: center;">pH = 2,85</p> <p style="text-align: center;">Aspect: in compliance / not in compliance</p>	<p>N ≥ 4</p> <p>Volume ≥ 12 ml</p> <p>pH = 2.81 ± 0.10</p> <p>Transparent, colorless</p>												
<p>c. Reactivity:</p> <p style="text-align: center;">N = 3 normal individuals</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">[collagen] (µg/ml)</th> <th style="text-align: center;">Mean % AgregMax</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">10</td> <td style="text-align: center;">86%</td> </tr> <tr> <td style="text-align: center;">2</td> <td style="text-align: center;">86%</td> </tr> </tbody> </table>	[collagen] (µg/ml)	Mean % AgregMax	10	86%	2	86%	<p>%AgregMax ≥ 70%</p> <p>%AgregMax ≥ 70%</p>						
[collagen] (µg/ml)	Mean % AgregMax												
10	86%												
2	86%												
<p>d. Stability of reconstituted reagent (tested at 2 µg/ml)</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Storage time and temperature:</th> <th style="text-align: center;">%AgregMax</th> <th style="text-align: center;">Δ%</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Freshly restored</td> <td style="text-align: center;">90%</td> <td style="text-align: center;">na</td> </tr> <tr> <td style="text-align: center;">24 hours at RT (18-25°C)</td> <td style="text-align: center;">86%</td> <td style="text-align: center;">4%</td> </tr> <tr> <td style="text-align: center;">7 days at 2-8°C</td> <td style="text-align: center;">84%</td> <td style="text-align: center;">6%</td> </tr> </tbody> </table>	Storage time and temperature:	%AgregMax	Δ%	Freshly restored	90%	na	24 hours at RT (18-25°C)	86%	4%	7 days at 2-8°C	84%	6%	<p>Δ% (%AgregMax stored/fresh)</p> <p>≤20%</p>
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<p>Comments :</p>	<p><input checked="" type="checkbox"/> Passed in Compliance</p>												

Date : 2017-01-17

QC Manager :

S. LECOURT