



Title: **NADMED-0011 and 0012**

Document type: **Certificate of Analysis**

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# 1. CERTIFICATE OF ANALYSIS

**Product:** Q-NADMED blood kit

**Catalog number:** IVD - 001

**Lot:** 0011 and 0012

**Specification:** Performance evaluation upon manufacturing

**Tested parameters:**

1. UV-Vis spectra of NAD+ and/or NADH standard stocks
2. Performance of the Standards in the assay
3. Volume of individual components in the kit

**Status:** All parameters are within reference range

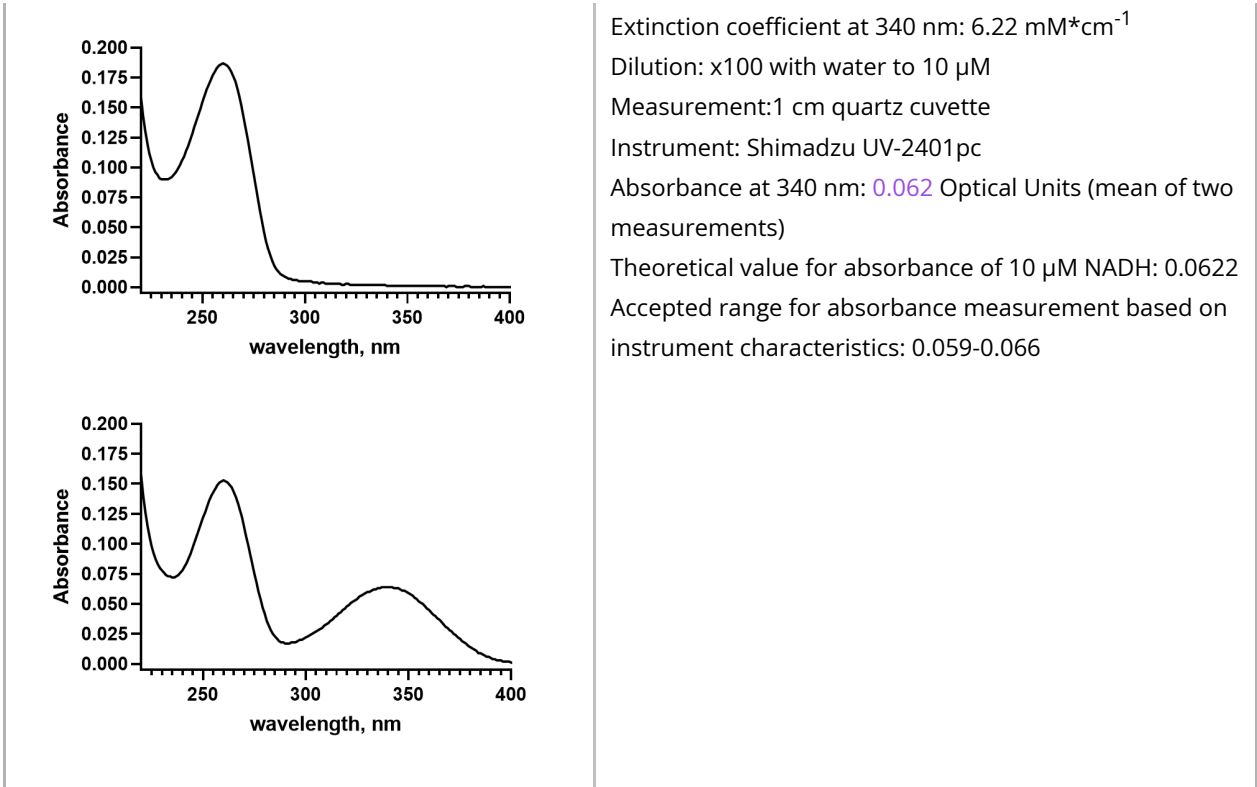
**Date:**

**Approved** by Chief Scientific Officer, Liliya Euro, PhD



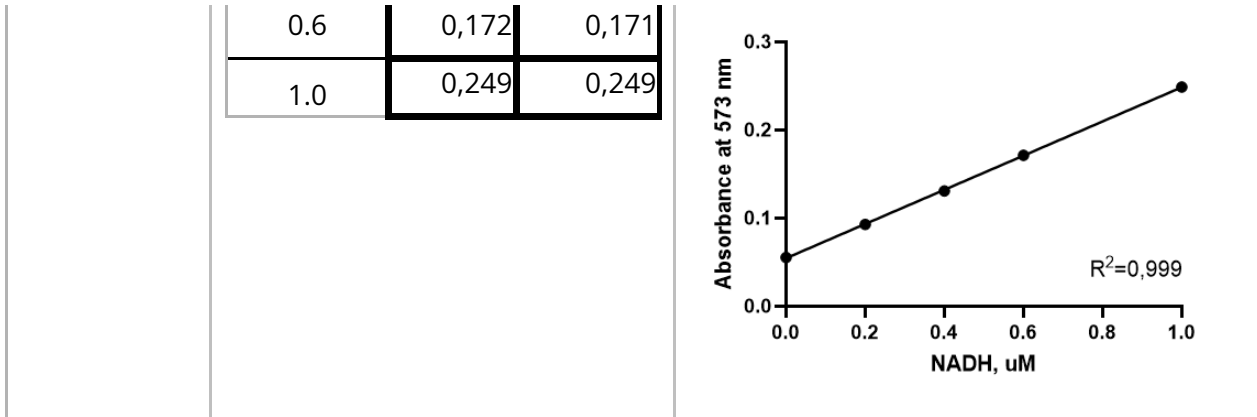
## 2. Summary of UV-Vis spectroscopy analysis of kit standards

<b>Summary of UV-Vis spectroscopy analysis of kit standards</b>	
Purpose: measurement of compound concentration in NAD+ and NADH standard stocks	
	Standard: 1 mM NAD+ Extinction coefficient at 260 nm: 18 mM*cm <sup>-1</sup> Dilution: x100 with water to 10 µM Measurement: 1 cm quartz cuvette Instrument: Shimadzu UV-2401pc Absorbance at 260 nm: 0,183 Optical Units (mean of two measurements) Theoretical value for absorbance of 10 µM NAD+: 0.180 Accepted range for absorbance measurement based on instrument characteristics: 0.178 - 0.185  Standard: 1 mM NADH



### 3. Summary of Standard performance in the assays

Assay	Absorbance at 573 nm	Standard curve fitting																		
<b>NAD+ Standards</b>	Reaction time - 4 min 10 sec																			
	<table border="1"> <thead> <tr> <th>NAD+, uM</th> <th>1 meas</th> <th>2 meas</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0,054</td> <td>0,053</td> </tr> <tr> <td>1</td> <td>0,212</td> <td>0,207</td> </tr> <tr> <td>2</td> <td>0,356</td> <td>0,349</td> </tr> <tr> <td>3</td> <td>0,549</td> <td>0,501</td> </tr> <tr> <td>5</td> <td>0,826</td> <td>0,79</td> </tr> </tbody> </table>		NAD+, uM	1 meas	2 meas	0	0,054	0,053	1	0,212	0,207	2	0,356	0,349	3	0,549	0,501	5	0,826	0,79
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<b>NADH Standards</b>	Reaction time - 6 min																			
	<table border="1"> <thead> <tr> <th>NADH, uM</th> <th>1 meas</th> <th>2 meas</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0,057</td> <td>0,054</td> </tr> <tr> <td>0.2</td> <td>0,095</td> <td>0,091</td> </tr> <tr> <td>0.4</td> <td>0,134</td> <td>0,128</td> </tr> </tbody> </table>	NADH, uM	1 meas	2 meas	0	0,057	0,054	0.2	0,095	0,091	0.4	0,134	0,128							
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### 4. Criteria for acceptance assay performance results

Parameter	Reference values	Quality Control
Absorbance range for 0 - 5 µM NAD+ Assay Standards (assay time 4 min)	0.04 - 0.800 Accepted variation between replicates - 0.05 Optical Units	passed
Absorbance range for 0 - 1 µM NADH Assay Standards (assay time 6 min)	0.04 - 0.260 Accepted variation between replicates - 0.05 Optical Units	passed
R <sup>2</sup> of liner fit for NAD+ standard curve	>0.99	passed
R <sup>2</sup> of liner fit for NADH standard curve	>0.99	passed
Volumes of single components were enough to perform two 96-well plate assays	Yes	passed

### 5. Attachments