

16. REFERENCE RANGES

Reference ranges (95%) were estimated using samples obtained from adult individuals of diverse races. Each laboratory shall establish their own range of reference values. ND = Not detectable; lower than the LoD.

Group	N	Median (pg/ml)	95% Reference Range (pg/ml)
Adult Males (20 – 89 years old)	304	380	143 – 842
Adult Females (18 – 50 years old)	183	91	ND – 596
Adult Females (51 – 83 years old)	135	53	ND – 431

Reference ranges were estimated using pediatric samples as shown below. Due to the limited sample size, a 95% reference range could not be established; the total range is provided. Each laboratory shall establish their own range of reference values.

Gender	Age (Years)	N	Total Range (pg/ml)
Male	1 – 9	40	ND – 85.7
	10 – 14	26	11.1 – 875.6
	15 – 18	14	70.3 – 1260.9
Female	2 – 9	40	ND – 88.9
	10 – 14	21	22.5 – 280.6
	15 – 18	19	62.6 – 760.3

17. LITERATURE

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- Gorityala, S., Yang, S., Montano, M. M., & Xu, Y. (2018). Simultaneous determination of dihydrotestosterone and its metabolites in mouse sera by LC-MS/MS with chemical derivatization. *Journal of chromatography. B, Analytical technologies in the biomedical and life sciences*, 1090, 22–35. <https://doi.org/10.1016/j.jchroomb.2018.05.008>
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18. CHANGE HISTORY

Previous Version:	2.0	New Version:	3.0
Changes:	New IFU format with numbered headings.		
	<p>1. INTENDED PURPOSE & USE Addition: This kit is intended for professional use only and is for laboratory use only. For <i>research</i> use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.</p> <p>2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE 1 and 2 added.</p> <p>5. PROCEDURAL CAUTIONS AND WARNINGS Additional cautions and warnings added. Some previous limitations added to this section.</p> <p>8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED Addition of Automatic microplate washer.</p> <p>11. ASSAY PROCEDURE Component names revised to match symbol definitions.</p> <p>13. QUALITY CONTROL New section added.</p> <p>15.4 PRECISION Reproducibility New section/data added.</p> <p>18. CHANGE HISTORY New section added.</p> <p>Addition of product complaints, warranty and limitation of liability sections.</p>		

Product Complaints

In the case of product complaints, the user shall submit in writing to the distributor or manufacturer a description of the complaint and provide accompanying data and/or information.













Warranty

The manufacturer guarantees that the product is free of defects and will perform within the product specifications when the product is used prior to the expiration date, according to the intended purpose and use, and according to the instructions for use provided with the product. Any deviations from the intended purpose and use, instructions for use, modifications to kit components or use beyond the expiration date will invalidate any warranty claims.

Limitation of Liability

The manufacturer liability in all circumstances whether in tort (including negligence) or at common law, and for any damage or loss, including but not limited to loss of profit and loss of sales, suffered whether direct, indirect, consequential, incidental or special is limited to the purchase price of the product(s) in question.

Symbols:

	Storage temperature		Manufacturer		Contains sufficient for <n> tests
	Use-by date		Batch code		
	Consult instructions for use		Content		
	Caution		Catalogue number		Distributor
	Date of manufacture				For research use only!