Certificate Of Analysis



Orphée S.A. assures that this reagent batch was manufactured under control of proper Quality Management System (ISO 13485).

Each batch undergoes a series of stringent validation and control tests

Product: Only One
Reference: HM22-002-1
Batch number: 1939
Use Before: 22-September-2021

Tested on: September 24, 2019

Tested by: J. GIRAUD

Tested with: Mythic 22 Nb: 200518-002286

Other Reagents: ORPHEE HM22-001-1 Lot number: 904-26 Exp date: 2021-06-30

ORPHEE HM22-003-10 Lot number: 906-86 Exp date: 2021-07-31

L MYT1910 Exp date: 2019-12-05

Hematology Controls Lot number: N MYT1910 Exp date: 2019-12-05

H MYT1910 Exp date: 2019-12-05

Specifications Conclusion

Osmolarity: 335±10 Pass

Physico-Chemical properties •pH at 25°C: 6.55±0.10 Pass

*Conductivity (mS.cm⁻¹): 17.0±1.0 Pass

Bio-Chemical efficiency Performance Tests: Pass

Conclusion:

Actual-value meets specifications

Date: 25.09.2019

Prepared by Anna Spryszak / QC

Date: 25.09.2019

Approved by Robert Wiśniewski / QMS Representative

19, chemin du Champ-des-Filles – CH-1228 PLAN-LES-OUATES / GENEVA / SWITZERLAND

Phone: +4122 884 90 90 - Fax: +4122 884 90 99

WEB: www.orphee-medical.com-Email: contact@orphee-medical.com