

ISO/TS 17518:2015-04 (E)

Medical laboratories - Reagents for staining biological material - Guidance for users

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Acquiring reagents for in vitro diagnostic staining in biology	8
4.1 General principles	8
4.2 Manufacturer name	8
4.3 Identification of kit components	8
5 Information associated with the in vitro diagnostic reagent	8
5.1 Intended use	8
5.2 Instructions for use	9
5.3 Identification of the reagent for staining of biological samples	9
5.3.1 Reagent name	9
5.3.2 Description of IVD reagent for staining of biological samples	10
5.3.3 Batch code	10
5.3.4	10
5.4 Storage and handling conditions	10
5.5 Expiry date	10
5.6 Warnings and precautions	11
5.7 Additional information for specific kinds of reagents	11
5.7.1 Fluorochromes	11
5.7.2 Metal salts	11
5.7.3 Additional required equipment	11
5.7.4 Reagent preparation	11
5.7.5 Control procedure	11
5.7.6 Interpretation	12
5.7.7 Limitations of the examination procedure	12
5.7.8 Literature references	12
6 Validation and verification of biological stains	12
6.1 General Information	12
6.2 Validation for the intended use	13
6.3 Verification of the specifications	13
6.4 Certification of biological dyes	13
6.5 Acquisition of biological stains and dyes	13
Annex A (informative) Checklist for establishing or verifying specifications for biological stains and dyes	14
Bibliography	15