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 Termsanddefinitions 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 Validationandverificationofbiologicalstains 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)Checklistforestablishingorverifyingspecificationsforbiological stains and dyes 14

Bibliography 15