

# ISO/TS 17518:2015-04 (E)

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

---

<b>Contents</b>		<b>Page</b>
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