

---

---

**In vitro diagnostic medical devices —  
Information supplied by the  
manufacturer with in vitro diagnostic  
reagents for staining in biology**

*Dispositifs médicaux de diagnostic in vitro — Informations fournies  
par le fabricant avec les réactifs de coloration de diagnostic in vitro  
utilisés en biologie*



Reference number  
ISO 19001:2013(E)

© ISO 2013



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Requirements for information supplied by the manufacturer</b> .....	<b>3</b>
4.1 General requirements .....	3
4.2 Additional requirements for specific kinds of reagent .....	4
<b>Annex A (informative) Examples of information supplied by the manufacturer with reagents commonly used in biological staining procedures</b> .....	<b>7</b>
<b>Bibliography</b> .....	<b>13</b>

This document is a part of the ISO 19001 series of standards.