

# ISO 24190:2023-05 (E)

## Biotechnology - Analytical methods - Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	General considerations .....	7
5	Risk management for microbiological contamination .....	7
5.1	Risk management in manufacturing process .....	7
5.2	Risk management in microbial testing .....	8
6	Selection of a fit-for-purpose assay .....	9
6.1	General .....	9
6.2	Assay selection .....	10
6.3	Kit or system selection .....	10
6.4	Considerations for various test types .....	11
6.5	User requirement specifications .....	12
6.5.1	General .....	12
6.5.2	Speed .....	12
6.5.3	Sample volume .....	12
6.5.4	In-process versus final release testing .....	12
6.5.5	Specificity .....	12
6.5.6	Sensitivity .....	13
7	Validation .....	13
7.1	General concepts .....	13
7.2	Selection of microorganisms for validation .....	14
7.3	Quality by design of method validation .....	15
7.4	Revalidation method .....	15
7.5	System validation .....	16
7.6	Use of reference material in validation .....	16
7.7	Acceptance criteria of targeted validation parameters .....	16
7.8	Precision .....	17
7.9	Detection limit .....	17
7.10	Accuracy .....	17
7.11	Robustness .....	18
7.12	Ruggedness .....	18
8	Use and application of rapid microbial tests .....	18
8.1	Number and type of samples .....	18
8.2	Testing environment .....	18
8.3	Sensitivity .....	19
8.4	Analytical specificity (microorganism detection) .....	19
8.5	Comparable test data .....	19
9	Investigation of positive sterility results .....	20

<b>10</b>	<b>Training .....</b>	<b>20</b>
<b>11</b>	<b>Documentation .....</b>	<b>21</b>
<b>12</b>	<b>Test report .....</b>	<b>21</b>
	<b>Annex A (informative) Exemplary framework for identifying microbial contamination .....</b>	<b>22</b>
	<b>Annex B (informative) Risk analysis with cellular therapeutic products related to input materials -- Donor selection .....</b>	<b>23</b>
	<b>Annex C (informative) Risk analysis with cellular therapeutic products related to input materials -- Cell transformation and expansion .....</b>	<b>24</b>
	<b>Annex D (informative) Risk analysis with cellular therapeutic products related to input materials -- Packaging storage and administration .....</b>	<b>26</b>
	<b>Annex E (informative) Risk-based classification for monitoring practices for cellular therapeutic product manufacturing .....</b>	<b>27</b>
	<b>Annex F (informative) Validation of rapid microbial test methods .....</b>	<b>28</b>
	<b>Annex G (informative) Microorganisms for validation of rapid microbial test methods .....</b>	<b>30</b>
	<b>Annex H (informative) Methods for rapid microbial testing .....</b>	<b>34</b>
	<b>Annex I (informative) Environmental control .....</b>	<b>41</b>
	<b>Bibliography .....</b>	<b>42</b>