

Appendix 9. Essential Reference Organisms and Toxins*

Genus	Species/Serotype	Strain	Source	Additional Recommended Species/Strains			Exclusivity Species
				Species	Strain/Serotype	Source	
<i>Aeromonas</i>	<i>A. hydrophila</i>	ATCC@ 49140 TM	ATCC@				
	<i>A. hydrophila</i>	ATCC@ 7965 TM	ATCC@				
<i>Bacillus anthracis</i> Controlled Access	<i>B. anthracis</i>	AMC strain	BEI Resources				
	<i>B. anthracis</i>	Ames strain	BEI Resources				
	<i>B. anthracis</i>	Davis	BEI Resources				
	<i>B. anthracis</i>	Kruger B1	BEI Resources				
<i>Bacillus cereus</i>	<i>B. cereus</i>	ATCC@ 13061 TM	ATCC@				
	<i>B. cereus</i>	ATCC@ 13061 TM	ATCC@				
	<i>B. cereus</i>	ATCC@ 10876 TM	ATCC@				
	<i>B. cereus</i>	enterotoxigenic producing strains - FDA TJL-14	FDA				
	<i>B. cereus</i>	emetic toxin producers	Pending final method research				
<i>Brucella</i> Controlled Access	<i>B. abortus</i> (CO2 dependent and independent)		BEI Resources				
	<i>B. canis</i>		BEI Resources				
	<i>B. melitensis</i>		BEI Resources				
	<i>B. suis</i>		BEI Resources				
<i>Campylobacter</i>	<i>C. fetus subsp. fetus</i>	ATCC@ 15296 TM	ATCC@				
	<i>C. jejuni subsp. jejuni</i>	ATCC@ 33291 TM	ATCC@				
	<i>C. coli</i>	ATCC@ 43478 TM	ATCC@				
	<i>C. upsaliensis</i>						
	<i>C. jejuni subsp. venerealis</i>	ATCC@ 19438 TM	ATCC@				
	<i>C. lari</i>	ATCC@ 35222 TM NCTC 11457	ATCC@/ NCTC				
	<i>C. jejuni</i> subspecies <i>doylei</i>	ATCC@ 49351 TM NCTC 11924	ATCC@/NCTC				
	<i>C. jejuni</i> subspecies <i>jejuni</i>	CIP 702	BEI Resources				
	<i>C. jejuni</i> subspecies <i>jejuni</i>	NCTC 11168	BEI Resources				
<i>Clostridium</i>	<i>C. perfringens</i>	ATCC@ 3624 TM	ATCC(r)				Requires Export permit outside of the US
	<i>C. perfringens</i> Hobbs serotype 2	NCTC 8238					Requires Export permit outside of the US
	<i>C. perfringens</i> Hobbs serotype 3	NCTC 8239					Requires Export permit outside of the US
	<i>C. perfringens</i> Hobbs serotype 13	NCTC 10240					Requires Export permit outside of the US
	<i>C. perfringens</i>	ATCC@ 12919 TM	ATCC@				Requires Export permit outside of the US
	<i>C. botulinum</i> Type A	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 25763 TM
	<i>C. botulinum</i> Type B	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 17848 TM
	<i>C. botulinum</i> Type E	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 9564 TM
	<i>C. botulinum</i> Type F	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 35415 TM
	<i>C. butyricum</i> Type E	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 43755 TM
	<i>C. argentinense</i> Type G	No longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 27322 TM
<i>Coxiella burnetii</i>							
<i>Cryptosporidium</i>	<i>C. parvum</i> (For DNA only)	PRA-67D, IOWA strain	ATCC@ or Waterborne, Inc.				
	<i>C. parvum</i> (Oocyst)	IOWA strain	Bunch Grass Farm				
	<i>C. parvum</i> (bovine genotype)	IOWA strain					
	<i>C. hominis</i>						
<i>Cyclospora</i>	<i>C. cayetanensis</i>	Any isolates from feces from naturally infected individuals. Currently, no isolate or strain is maintained in a laboratory.					
<i>Enterobacter sakazakii</i>	<i>E. sakazakii</i>	ATCC@ 51329 TM	ATCC@				
	<i>E. aerogenes</i>	ATCC@ 13048 TM	ATCC@				
<i>Escherichia coli</i>	<i>E. coli</i> Biotype1	ATCC@ 11775 TM	ATCC@				
	<i>E. coli</i> Biotype1	ATCC@ 51813 TM	ATCC@				
	<i>E. coli</i>	ATCC@ 25922 TM	ATCC@				
	<i>E. coli</i>	ATCC@ 8739 TM	ATCC@				
(Pathogenic)	<i>E. coli</i> O157:H7 (toxin negative)	ATCC @ 43888 TM	ATCC@				
	<i>E. coli</i> O157:H7 (toxin positive) VT1 or VT2?	no longer available from ATCC@ or by reference strain number	BEI Resources				former ATCC@ 43894

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	<i>E. coli</i> O157:H7 (EDL 931) Non O157:H7 EHEC strains Shigella STX gene	no longer available from ATCC® or by reference strain number		former ATCC® 35150			
<i>Giardia</i>	<i>G. lamblia</i> <i>G. muris</i>	Human Isolate H3 P101		Waterborne, Inc			
<i>Helicobacter pylori</i>							
<i>Listeria</i>	<i>L. monocytogenes</i> ½ a <i>L. monocytogenes</i> ½ a <i>L. monocytogenes</i> ½ b <i>L. monocytogenes</i> ½ c <i>L. monocytogenes</i> 3a <i>L. monocytogenes</i> 4b <i>L. monocytogenes</i> 4b <i>L. monocytogenes</i> 4d <i>L. monocytogenes</i> <i>L. monocytogenes</i> (non-hemolytic) <i>L. ivanovii</i> 5 <i>L. innocua</i> 6a <i>L. welshimeri</i> 6b <i>L. seeligeri</i> <i>L. grayi</i> <i>L. grayi</i>	ATCC® 51772™ ATCC® 51775™ ATCC® 51780™ ATCC® 51779™ ATCC® 51782™ Scott A ATCC® 19115™ ATCC® 19117™ ATCC® 19111™ ATCC® 15313™ ATCC® 19119™ ATCC® 33090™ ATCC® 35897™ ATCC® 35967™ ATCC® 25400™ ATCC® 25401™		ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC® ATCC®			
<i>Mycobacterium paratuberculosis</i>			BEI Resources	Controlled Access Strain			
<i>Norovirus</i>	Norwalk – Group I Snow Mountain Agent – Group II	Any isolates from feces from naturally infected individuals. Currently, no isolate or strain is maintained in a laboratory.					
<i>Salmonella</i>	<i>Salmonella</i> Typhi <i>Salmonella</i> Paratyphi A <i>Salmonella</i> Paratyphi B <i>Salmonella</i> Paratyphi C <i>Salmonella</i> Sendai <i>Salmonella</i> Typhimurium <i>Salmonella</i> Enteritidis <i>Salmonella</i> choleraesuis	ATCC® 13311™ ATCC® 13076™ ATCC® 10708™		ATCC® ATCC® ATCC®		Representatives from somatic groups B-I Representatives from "further groups" H2S negative strain (>48 hours)	
	<p>1. A minimum of 35 of the top 50 serotypes isolated in the United States from 1968 to 1998 (see attached table An Atlas of Salmonella in the United States, published by the CDC in 2000.</p> <p>2. Representatives from somatic groups B-I (serotypes should be evenly distributed across the groups). A minimum of 30 serotypes seems appropriate.</p> <p>Representatives from "further groups". These further groups should also include representative serotypes from the <i>enterica</i> subspecies <i>salamae</i> (II), <i>arizonae</i> (IIIa), <i>diarizonae</i> (IIIb), <i>houtenae</i> (IV), and <i>indica</i> (VI). <i>S. bongori</i> should also be included if possible.</p>						
<i>Shigella</i>	<i>S. boydii</i> serotype 2 <i>S. dysenteriae</i> <i>S. flexneri</i> serotype 2a <i>S. sonnei</i> WRAIR I virulent	NCTC 12985 NCTC 4837 24570		BEI Resources BEI Resources BEI Resources BEI Resources			
<i>Staphylococcus</i>	<i>S. aureus</i> <i>S. aureus</i> <i>S. epidermidis</i>	ATCC® 25923™ ATCC® 6538™ ATCC® 12228™		ATCC® ATCC® ATCC®			
Staphylococcal Enterotoxins	A B C1 C2 C3 D	FRI-722 (FDA) 110-270USAMRIID FRI 137 (FDA) FRI 361 (FDA) FRI 1230 (FDA) FRI 1151 (FDA)		Toxin Technology Toxin Technology Toxin Technology Toxin Technology Toxin Technology Toxin Technology			

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	E	FRI 326 (FDA)	Toxin Technology				
	F (Toxic shock toxin)	RFDA 485 (A,B,D) (FDA)	Toxin Technology				
	Non-toxicogenic strain	FDA D87	FDA				
		FDA D184	FDA				
		<i>S. interimidis</i>	FDA				
Vibrio	<i>V. cholerae</i>	7 th pandemic O1 strain					
	<i>V. cholerae</i>	O139 (7 th pandemic strain that has mutated to have a capsule)					
	<i>V. cholerae</i>	non-O1/non-O139/non-toxicogenic strain					
	<i>V. cholerae</i>	Gulf Coast O1 toxigenic strain (non-epidemic)					
	<i>V. cholerae</i>	classical <i>cholerae</i> strain					
	<i>V. cholerae</i>	O141 toxigenic strain that has recently emerged					
	<i>V. parahaemolyticus</i> O3:K6						
	<i>V. parahaemolyticus</i> O4:K12	tdh+/trh+					
	<i>V. parahaemolyticus</i>	non-pathogenic strain (tdh-/trh-)					
	<i>V. parahaemolyticus</i>	clinical strain (tdh-/trh+)					
	<i>V. vulnificus</i> , biotype 1 (rRNA type B)						
	<i>V. vulnificus</i> , biotype 2 (rRNA type A)						
	<i>V. vulnificus</i> biotype 3 (rRNA type A/B)						
Yersinia	<i>Y. enterocolitica</i>	ATCC® 27729™	ATCC®				

* This table presents a reasonably comprehensive inclusivity list of reference pathogenic and related microbiological species and toxins that must be included in any validations study. Other strains used for inclusivity or exclusivity must be characterized using nationally or internationally accepted reference methods. The pre-collaborative and/or collaborative study protocols submitted by method developers or study directors for review, will be evaluated by an expert panel to ensure that the strains selected for exclusivity include a sufficient number of appropriate "nearest-neighbours" to also challenge the inclusivity of the method.