Index

3M Rapid Detection Flu A+B Test 91
AAVLD see American Association for Veterinary Laboratory Diagnosticians
Abbott m2000sp system 440–441
Abbott PLEX-ID 103, 105, 240, 457
Abbott RealTime 140–141, 181–182
ABI SOLiD 453
Accelerate ID/AST System 452–453
AccuProbe 236–237, 279
acid-fast bacilli (AFB) 399–400
acid-fast staining reagents 273–274
acquired immunodeficiency syndrome see HIV/AIDS
adenovirus (ADV) molecular tests 98–99, 105–107, 110–112
rapid devices and instruments 94–95
serological reagents 2
AdvantDx QuickFISH System 448
aerobic bacteria automated systems 22–29, 38–40
blood culture systems 46–48
commercial systems 22–42, 46–49
currently available technologies 21–29
direct fluorescent antibody testing 44–45
emerging technologies 49
fastidious Gram-negative organisms 44–46
fatty acid analysis with gas chromatography 22
Gram-negative organisms 38–46
Gram-positive bacilli 37–38
Gram-positive cocci 29–37
MALDI-ToF/MS 21, 22, 43–44, 49
manual systems 37, 38
molecular tests 21, 36, 45
peptide-nucleic acid fluorescent in situ hybridization 47
phenotypic testing 21
protein mass spectrometry 22
rapid devices and instruments 21–55
see also individual species
Aeromonas spp. 44
Aerospray TB Stainer 274
AFB see acid-fast bacilli
Affirm VP11 DNA probe 297–299
African tick bite fever (ATBF) 185
agar disk diffusion 253–257
dermatophytes 255
filamentous fungi 255–257
surveillance studies 254–255
agar gel immunodiffusion (AGID) assay 351–353, 363
agar gradient diffusion method 423–424
Agency for Healthcare Research and Quality (AHRQ) 460
AGID see agar gel immunodiffusion
AHRQ see Agency for Healthcare Research and Quality
AIDS see HIV/AIDS
AlbiQuick 227
Alere Shiga Toxin Chek/Quik Chek 42–43
AlphaTeC Systems 273–274
Amblyomma spp. 185, 191
AMBR see asynchronous magnetic bead rotation
American Association for Veterinary Laboratory Diagnosticians (AAVLD) 347
American Society for Microbiology (ASM) 436, 460–462
American Type Culture Collection (ATCC) type strains 200
AMPLICOR Respiratory Specimen Preparation Kit 274–275
AMPLIFIED MTD2 Test 274
anaerobic bacteria antigen detection 75–81, 82
collection, transport and storage of specimens 58–59
colonies 59–60, 64–71, 74, 77–82
cytotoxicity testing 74–81, 82
diagnosis of anaerobic bacterial infections 57–64
gas chromatography 73
gene sequencing 71
glutamate dehydrogenase tests 74, 75–78, 82
immunodiagnostic tests 74–81
incubation, inspection and subculture of colonies 59–60
interpretation of anaerobe identification results 70–71
MALDI-ToF/MS 71–73
molecular tests 74–75, 81–82
PCR-ESI/MS 73
phenotypic testing 61
preparation of inocula 65–67
presumptive identification and characterization of anaerobes 60–63
rapid devices and instruments 56–86
see also individual species
analyte-specific reagents (ASR) 106, 108–109, 112
Anaplasm spp. 188–189
Angiostrongylus vasorum 368
ANMAT (Argentina) 475–477, 481
ANSM (France) 507, 514
anthrax 433
antibiotic stewardship 461–462
antibody detection clinical veterinary microbiology 351–354, 369–370
in vitro diagnostic devices 517
mycoplasma 203–205
antigen detection clinical veterinary microbiology 354–355, 369
identification and susceptibility testing of fungi 215–216
identification of anaerobic bacteria 75–81, 82
identification of viruses 87, 89–90, 92, 98
in vitro diagnostic devices 517
mycoplasma 203–205
viral hepatitis 129
antimicrobial susceptibility testing (AST) 414–432
automated broth microdilution 415–422
BIOMIC V3 Microbiology System 423, 424–425
correlations and definitions 414–415
definitions 414–415
evaluation of commercial AST performance 415
FilmArray Blood Culture Identification panel 427–428
future directions 451–453
genotypic detection in positive blood cultures 427–428
manual agar gradient diffusion method 423–424
manual disk diffusion test 424
MicroScan AutoScan 4 system 422
MicroScan WalkAway plus system 416, 418–419
minimal inhibitory concentration 414–415, 417–425
mycoplasma 209–210
next generation methods 428–430
phenotypic testing using chromogenic media 425–427
Phoenix Automated Microbiology System 416, 419–420
plate readers 423
automated and manual broth microdilution AST systems 422–423
Sensititre ARIS 2X 416, 420–422
Sensititre OptiRead Fluorometric Plate Reading System 422–423
Sensititre Vizion Digital MIC Viewing System 423
SIRSCAN 2000 System 425
Verigene blood culture systems 428
Vitek 2 system 416–418
Xpert MRSA/SA blood culture assay 427
APHL see Association of Public Health Laboratories
API systems 33–34, 37, 227–229, 236, 361
AP-PCR see arbitrarily-primed PCR
APTIMA HPV assay 140
APV see avian pneumovirus
arbitrarily-primed PCR (AP-PCR) 336
Argentina 475–482
registration requirements 477
automated broth microdilution 415–422
BACTEC systems 15–17, 221–222, 223, 276–277, 280–281
bacteriology see aerobic bacteria; anaerobic bacteria; antimicrobial susceptibility testing; rapid devices and instruments
Bacteroides spp. 56–57, 65, 68–69
BactiCard 226–227
Baermann technique 368
bandwagon effect 384
BBL Crystal ID systems 29, 66, 69–70
BBL Sensi-Disk 280
BD Directigen EZ Flu A+B 90
BDG see 1,3-beta-D-glucan
BD GeneOhm Cdiff 81–82
BD Max System 36
BD MycoPrep 273–274
bDNA see branched DNA
BD Phoenix Yeast ID Panel 236
BD ProbeTec CT Qx 181–182
BD Veritor System 90–91
BD Viper HPV test 141
Becton Dickinson see BD
benefit-risk determinations 3–4
1,3-beta-D-glucan (BDG) 219
BIGGY see bismuth sulfite glucose glycine yeast
BIMO see Bioresearch Monitoring Program
BionaxNOW 35, 90
BioFire FilmArray systems 48, 102–103, 107, 300–301, 427–428, 444
Bilog MicroPlate systems 32, 74, 236
bioMérieux see Vitek
BIOMIC V3 Microbiology System 423, 424–425
Bio-Rad Platelia
Bio-Rad Platelia Agarose 58
Bio-Rad Platelia Con A
bioanalytical systems 320–332
biobanks 462
biorepositories 462
Bioresearch Monitoring Program (BIMO) 4
bioterrorism 433–437
concepts and definitions 433
diagnostic laboratories 433, 435–436
future developments 434–435
historical development 433–434
Laboratory Response Network 433, 435–436
rapid devices and instruments 436
bismuth sulfite glucose glycine yeast (BIGGY) agar 226
BK virus (BKV) 110–112
blood collection 303–305
blood culture systems 11–20
antimicrobial susceptibility testing 427–428
automated blood culture systems 12–18, 222–224, 276–277
BacT/Alert 13–15, 222–223, 277
BactiCard 226–227
Baermann technique 368
bandwagon effect 384
media for isolation and identification 224–226
molecular and other methods 18–19
mycobacteria 275–278
Oxoid Signal 12
rapid devices and instruments 46–48
SEPTI-CHEK 11–12, 276
VersATREK 17–18, 222, 224, 277–278
blood stream infections (BSI) 427–428
BMD see broth microdilution
bocavirus (BoV) 98–99, 400
Bordetella spp. 44–45
Borreia burgdorferi 186–187
B. miyamotoi
clinical manifestations 396
emerging infectious diseases 396–397
epidemiology 396
transmission and risk factors 396–397
tracheitis 397
BSI see blood stream infections
CALAS see Cryptococcal Antigen Latex Agglutination System
Calcivirus 94–95
Campylobacter spp. 42–43
Canada 491–493
Candida spp.
blood culture systems 15, 18, 220–226
direct microscopic methods 217–218, 219–220
molecular tests 237–248
rapid devices and instruments 226–236
susceptibility testing 248–261
Cand-Tek Latex Agglutination test 217–218
CAP see College of American Pathologists; community-acquired pneumonia
capillary sequencing 451
carbapenem-resistant Enterobacteriaceae (CRE) 425, 426–427
CCFA see Cycloserine Cefoxitin Fructose Agar
CDC see Centers for Disease Control and Prevention
CDSCO see Central Drugs Standards Control Organization
CE see Conformité Européenne
cell culture
Chlamydia trachomatis 180
commercial growth media and diagnostic kits 198–202
identification of viruses 98, 109
mycoplasma 197
specimen collection and transport 198
specimens appropriate for culture 197–198
tick-borne diseases 191
cellular fatty acid (CFA) analysis 73
Centers for Disease Control and Prevention (CDC)
bioterrorism 435
Chlamydia trachomatis 175
diagnostic medical parasitology 287
emerging infectious diseases 392
future directions 460–461
HIV/AIDS 151–152
identification of viruses 88
rapid devices and instruments 61, 65
Central Drugs Standards Control Organization (CDSCO) 515–517
Cepheid GeneXpert 33, 100, 181, 274–275, 443–444
Cepheid SmartCycler 46, 101, 104
Cepheid Smart GBS 36
Cepheid Xpert 36, 46, 79–82, 100–104, 108–109, 182, 427
cervical intraepithelial neoplasia (CIN) 135–136
Cervista HPV 140, 141–142
CF see complement fixation
CFA see cellular fatty acid
chicken 525
China
commercial systems 495–506
in vitro diagnostic devices 494–506
product certification 495
product classification and registration procedure 494–496
regulatory requirements and product information 494–504
State Food and Drug Administration 494–496
Chiron RIBA HCV 3.0 Strip Immunoblot Assay 130
Chlamydia trachomatis 175–183
biology and life cycle 177–178
clinical manifestations 175, 178–179
clinical veterinary microbiology 363–364
commercial systems 181–182
detection and monitoring methods 175–176, 177, 179–182
epidemiology 175, 176–177
laboratory tests 179–182
natural history 178
non-nucleic acid amplification tests 175, 180
nucleic acid amplification tests 175–182
treatment 178, 179
Chlamylege multiplex PCR assay 208
CHROMagar 224–226, 258
ChromID 224
chromogenic media 425–427
CIN see cervical intraepithelial neoplasia
circulating recombinant forms (CRF) 150
cleavage technology 313
CLIA see Clinical Laboratory Improvement Amendments of 1988
Clinical and Laboratory Standards Institute (CLSI)
antimicrobial susceptibility testing 414, 417
clinical veterinary microbiology 346
future directions 438
identification and susceptibility testing of fungi 248–261
laboratory information systems 377, 379
mycobacteria 280
Clinical Laboratory Improvement Amendments of 1988 (CLIA) 6
bioterrorism 435
diagnostic medical parasitology 284–285
future directions 440
molecular tests 113
rapid devices and instruments 88, 92
clinical veterinary microbiology 346–376
agar gel immunodiffusion assay 351–353, 363
anaerobic bacteria 361–362
antigen-capture ELISA 354
assays for detection of antiviral antibodies 351–354
assays for detection of viral antigen 354–355
assays for detection of viral nucleic acids 355–358
assays for detection of virus 350–351
assays for genetic characterization and differentiation 358–359
automated systems 359–360
bacteriology identification systems 359
canine and feline heartworm 369–370
Chlamydia spp. 363–364
collection and transportation of clinical samples 347–348
complement fixation test 353
concepts and definitions 346–347
dot blot hybridization 355
ectoparasitology 371
electron microscopy 350
Enterobacteriaeae 360
enzyme-linked immunosorbent assay 349, 351, 354, 360–366
equipment 366–367
fetal specimen collection and examination 367–368
fluorescent antibody assay 353, 364–365
fluorescent microbead-based immunoassay 354
Gram-positive bacteria 361
hemaggglutination inhibition assay 353
immunofluorescence assay 354
molecular assays 354–355, 364, 371
in situ hybridization 355–356
latex agglutination test 355, 361
Mycobacterium spp. 362–363
mycoplasma 362
clinical veterinary microbiology (cont’d)
polymerase chain reaction 347, 349–350, 356–359, 363
quality control of diagnostic assays 349–350
rapid devices and instruments 361–363
restriction fragment length polymorphism 358–359
selection of diagnostic laboratories and tests 348–349
sensitivity and specificity 349–350
sequencing and sequence analysis 359
serological tests for protozoal parasites 369–370
serum virus neutralization 351
Southern blot hybridization 355
Spirochetes and spiral organisms 364
standard protocols 346
state and university-associated laboratories 365
Trichomonas foetus 370–371
vitamin D receptor sequence 326
virology 350–359
virus isolation and identification 350–351
weakly- and non-fermentative Gram-negative bacteria 360–361
Western blot 353
zoonotic pathogens 346–347, 364
Clostridium spp. 56–59, 67–69, 73–82
C. difficile
clinical manifestations 390
clinical veterinary microbiology 362
emerging infectious diseases 389–391
epidemiology 389–390
future directions 443–444, 448
rapid devices and instruments 74–81
transmission and risk factors 390
treatment and prevention 391
CLSI see Clinical and Laboratory Standards Institute
CMV see cytomegalovirus
Cobas 4800 HPV test 140
COBAS AmpliPrep 161–162
COBAS TaqMan Tests 112, 161–162, 274–275
cold agglutinins 202–203
College of American Pathologists (CAP)
future directions 438
laboratory information systems 379
molecular tests 111–112
Proficiency Testing Surveys 88, 92
viral hepatitis 128
Colorado tick fever virus (CTFV) 189–190
community-acquired pneumonia (CAP) 98
complement fixation (CF) 203, 353
concentration tests 369–370
Conformité Européenne (CE) 473, 507, 545
conformity assessments 485–486, 521, 524, 545
coronavirus (CoV) 97–99
Corynebacterium spp. 37–38
CoV see coronavirus
cPE see cytopathic effect
CRE see carbapenem-resistant Enterobacteriaceae
CRF see circulating recombinant forms
cryptic forms 218–219
Cryptococcal Antigen Latex Agglutination System (CALAS) 215–217
Cryptococcus spp.
clinical culture systems 17, 220–226
clinical manifestations 395
comparative studies 216–217
direct microscopic methods 214–217
emerging infectious diseases 394–396
enzyme immunoassay 216–217
epidemiology 394–395
lateral flow assay 216–217
latex agglutination tests 215–216
molecular tests 237, 243–245
rapid devices and instruments 228–236
susceptibility testing 248–261
transmission and risk factors 395
treatment and prevention 396
CSF see cerebrospinal fluid
CTFV see Colorado tick fever virus
Curetis Unyvero 447
cytomegalovirus (CMV) 93–94, 98–99
Cycloserine Cefoxitin Fructose Agar (CCFA) 75
cytology-based assays 136–137
direct fluorescent antibody (DFA) tests
180
Chlamydia trachomatis 180
diagnostic medical parasitology 294–297
diagnostic veterinary microbiology 366–367
emerging infectious diseases 389–391
identification of bacterial pathogens 44–45
identification of viruses 87, 92–93, 98
direct microscopic methods
Aspergillus spp. 218–220
1,3-beta-D-glucan 219
Candida spp. 217–218, 219–220
clinical veterinary microbiology 366–367
Cryptococcus spp. 214–217
dendritic mycoses 219–220
identification and susceptibility testing of fungi 214–220
direct nucleic acid probe 180
Dirofilaria immitis 369–370
disk diffusion test 424
disk readers 424–425
DLL see diffuse form of lepromatous leprosy
DNA extraction 246–248
DNA sequencing see sequencing
DOT see dermatophyte test medium
Duopath Verotoxin ICG 42
drug resistance
Chlamydia trachomatis 179
emerging infectious diseases 386
HIV/AIDS 165–167
mycobacteria 273, 274, 281
see also antimicrobial susceptibility testing
DOT see dermatophyte test medium
Duopath Verotoxin ICG 42
EAPCR see European Aspergillus PCR Initiative
EBM see evidence-based medicine
EBV see Epstein–Barr virus
ECL see electrochemiluminescence
ectoparasitology 371
EDMA see European Diagnostic Manufacturers Association
EHR see electronic health record
Ehrlichia spp. 188–189
emerging infectious diseases 386–413
see EM
EM see enzyme immunoassay; erythema migrans
EMB see eosin methylene blue
Emergency Use Authorization (EUA) 9–10
emerging infectious diseases 386–413
bocavirus 400
Borrelia miyamotoi 396–397
Clostridium difficile 389–391
concepts and definitions 386
Cryptococcus gattii 394–396
Escherichia coli 0104:H4 393–394
human metapneumovirus 400–402
Mycobacterium lepromatosis 398–400
pandemic H1N1 influenza 391–393
Plasmodium knowlesi 386–389
rapid diagnostic tests 388, 392
Rickettsia parkeri 397–398
severe fever with thrombocytopenia syndrome (SFTS) 402–403
tick-borne disease 191
Zika virus 403–404
emerging technologies
antibiotic stewardship versus laboratory stewardship 461–462
automated microscopy 452
capillary sequencing 451
commercial systems 442–447, 452–459
concepts and definitions 428–429
connectivity between extraction and amplification platforms 439–441
diagnostic and treatment strategies 459–460
digital PCR 443
DNA sequencing 451–452
integrated PCR assays 443–444
loop-mediated isothermal amplification 447–448
mass spectrometry 449–451
microbiological biorepositories 462
multiplex PCR/RT-PCR 444–447
next generation and high throughput sequencing 452–458
polymerase chain reaction and RT-PCR 441–447
probe technology 448
rapid devices and instruments 49
real-time PCR 441–443
responsibilities for the future 460–462
short read pyrosequencing 451–452
systematic reviews 460–461
total laboratory automation 458–459
transcription mediated amplification 447
endemic mycoses 219–220
Entamoeba histolytica 294–297
enteric viruses 105–107
Enterobacteriaceae
blood culture systems 16
clinical veterinary microbiology 360
rapid devices and instruments 38–39, 40–42
Enterococcus spp. 31–32, 34–37, 417–421
enterotoxins 389–390
enterovirus (EV) 99, 107–108
enzyme immunoassay (EIA)
automated immunoassay analyzers 319
Chlamydia trachomatis 180
diagnostic medical parasitology 294–297
emerging infectious diseases 390–391, 401
HIV/AIDS 151, 160–161
identification and susceptibility testing of fungi 216–219
identification of aerobic bacteria 40–43
identification of anaerobic bacteria 74–75, 77, 78–81
identification of viruses 87
mycoplasma 203–205
tick-borne diseases 186–188
enzyme-linked immunosorbent assay
(ELISA) antigen-capture ELISA 354
clinical veterinary microbiology 349, 351, 354, 360–366
emerging infectious diseases 401, 404
identification and susceptibility testing of fungi 216
identification of aerobic bacteria 40, 43
identification of viruses 89
tick-borne diseases 187–188, 190
enzyme-linked virus inducible system (ELVIS) 109
eosin methylene blue (EMB) agar 226
Epstein–Barr virus (EBV) 108–112
identification and susceptibility testing of Mycobacterium tuberculosis 386
European Aspergillus PCR Initiative (EAPCRI) 247–248
European Committee on Antimicrobial Susceptibility Testing (EUCAST) 414, 428
European Diagnostic Manufacturers Association (EDMA) 521
European Directive 98/79/EC 507, 514, 520, 537, 545
evidence-based medicine (EBM) 460
extended-spectrum beta-lactamase (ESBL) 425, 426
External Quality Assurance (EQA) 516
extremely drug resistant (XDR) tuberculosis 386
FA see fluorescent antibody
FADDL see Foreign Animal Disease Diagnostic Laboratory
Fasciola hepatica 369
Fast MicroSeq D2 LSU rDNA Fungal ID Kit 245–246
fatty acid analysis 22
FBI see Federal Bureau of Investigation
FDA see Food and Drug Administration
FDAMA see Food and Drug Administration Modernization Act of 1997
Federal Bureau of Investigation (FBI) 434, 435
FPFE see formalin-fixed paraffin-embedded
FIA see fluorescent immunoassay
filamentous fungi 255–257
FilmArray systems 48, 102–103, 107, 300–301, 427–428, 444
Flaviviruses 190
flotation techniques 297, 366–368
fluorescence resonance energy transfer (FRET) 314
fluorescent antibody (FA) assay 353, 364–365
fluorescent immunoassay (FIA) 90–91
fluorescent microbead-based immunoassay 354
Food and Drug Administration (FDA)
analytical performance characteristics 5–6
antimicrobial susceptibility testing 414, 417
assay interpretation 5
assay performance characteristics/statistics 101 for developers 7–8
Chlamydia trachomatis 175, 182
clinical performance 6–7
common issues with new submissions 8–10
current microbiology device review regulatory pathways 2–4
de novo petitions 3
device classification via Medical Device Amendment 1–2
device description 5
diagnostic medical parasitology 297–301
future directions 439
Food and Drug Administration (cont’d)
historical overview of in vitro diagnostics 1
HIV/AIDS 149, 156–157
human papillomaviruses 136–142
identification and susceptibility testing of fungi 214, 238–239
intended use of in vitro diagnostic devices 1–2, 473, 486
labeling 9
laboratory information systems 377, 379
major elements of IVD submission 5–7
molecular tests 97, 101, 104, 113
new and emerging pathogens and public health emergencies 9–10
new technologies 9
premarket amendment/application 3–4, 7, 9
premarket Notification 510(k) 2–3, 9
regulation of clinical microbiology devices 1–10
sensitivity and specificity 7
Food and Drug Administration Modernization Act of 1997 (FDAMA) 3
Foreign Animal Disease Diagnostic Laboratory (FADDL) 348
formalin 289–292
formalin-fixed paraffin-embedded (FFPE) tissue 247–248
France
ANSM regulatory requirements 507, 514
assessment procedures 514
commercial systems 508–513
European Directive 98/79/EC 507, 514
implications of regulatory level authorities 514
in vitro diagnostic devices 507–514
regulatory requirements and product information 507–514
Francisella tularensis 187–188
FRET see fluorescence resonance energy transfer
fungi 214–272
antigen detection 215–216
automated systems 222–224, 230–236
blood culture systems 220–224
commercial systems 229–230
direct examination and detection methods 214–220
identification of yeasts and yeast-like organisms 229–236
manual systems 220–222
media for isolation and identification 224–226
molecular tests 236–248
rapid devices and instruments 226–236
susceptibility testing 248–261
see also individual species
Fungitell assay 219
Fusarium spp. 218–219, 255–257
Fusobacterium spp. 65, 67
gas chromatography (GC) 22, 73
GDH see glutamate dehydrogenase gene sequencing see sequencing genetic microbiome 459–460
genetic studies 358–359
genital mycoplasma assays 205–206, 208–209
GenMark eSensor 446
GenMark Respiratory Virus Panel 102
Genome Sequence Scanning (GSS) 343
genomics 135
GenoType MTBDRplus 281
genotyping
antimicrobial susceptibility testing 427–428
HIV/AIDS 165–167
human papillomaviruses 141–143
viral hepatitis 130–131
GenPoint Catalyzed Signal Amplification System 138
Gen-Probe Aptima Combo 181–182
GenProbe hybridization probes 49
GHTF see Global Harmonization Task Force
Giardia spp. 285–286, 294–297, 368
GlabrataQuick 227–228
Global Harmonization Task Force (GHTF) 483–484
Global Medical Device Nomenclature (GMDN) 527
glutamate dehydrogenase (GDH) 74, 75–78, 82, 390–391
GMDN see Global Medical Device Nomenclature
Gram-positive organism identification (GPID) 29–37
GSS see Genome Sequence Scanning
Haemophilus spp. 17, 45
HAV see hepatitis A virus
HBoV see human bocavirus
HBV see hepatitis B virus
HCV see hepatitis C virus
HDV see hepatitis D virus
helicase-dependent amplification (HDA) 81–82, 312
Helicobacter spp. 43–44
hemagglutination inhibition (HI) 353
hematopoietic stem-cell transplant (HSCT) 401–402
hemolytic-uremic syndrome (HUS) 393–394
hepatitis A virus (HAV)
clinical manifestations 121
commercial systems 128
diagnostic considerations 123, 128
epidemiology 121–122
transmission and risk factors 122
treatment and prevention 123
hepatitis B virus (HBV)
clinical manifestations 122, 123–124
commercial systems 128–129
diagnostic considerations 123, 125, 128
epidemiology 121, 123–124
in vitro diagnostic devices 515–516
molecular tests 97, 112
transmission and risk factors 123
Treatment and prevention 123
hepatitis C virus (HCV)
clinical manifestations 122, 125
commercial systems 130–131
diagnostic considerations 125–126, 128
epidemiology 121, 124–125
in vitro diagnostic devices 515–516
molecular tests 112
transmission and risk factors 125
Treatment and prevention 126
hepatitis D virus (HDV)
clinical manifestations 122, 123–124
commercial systems 129
diagnostic considerations 128
epidemiology 121, 124
transmission and risk factors 124
Treatment and prevention 124
hepatitis E virus (HEV)
clinical manifestations 122, 126–128
commercial systems 131
diagnostic considerations 127, 128
epidemiology 121, 126–127
Treatment and prevention 127
Herpes Consensus Generic kit 109
herpes simplex virus (HSV) 93–94, 97–99, 108–109
Heterobilharzia americana 369
heterogeneous vancomycin intermediate S. aureus (hVISA) 430
HEV see hepatitis E virus
HHV see human herpesviruses
HI see hemagglutination inhibition
high-grade squamous intraepithelial lesions (HSIL) 136–137
high performance liquid chromatography (HPLC) 279
HIS see hospital information system
histopathological evaluation 349
Histoplasma spp.
blood culture systems 15, 17, 202–226
direct microscopic methods fungi 220
molecular tests 237
HIV/AIDS 149–174
antigen detection 151–152
automated immunoassay analyzers 319
commercial systems 149–150, 156–167
confirmatory and supplemental tests 157–159
diagnosis and management 149–150
drug resistance 165–167
enzyme immunoassay 151, 160–161
identification and susceptibility testing of fungi 214, 215
immunofluorescence assays 151, 159
in vitro diagnostic devices 484, 515–516
laboratory-based immunoassays 152–154, 156–157
markers of HIV infection 149–155, 157
molecular tests 97, 161–162
mycobacteria 273
neonates 159–160
nucleic acid amplification tests 149, 151–152
p24 antigen detection 149–151, 153–155, 157, 160–161
phenotypic and genotypic assays 165–167
point of care assays 154, 156–157, 163
qualitative molecular detection 161–162
quantification of HIV RNA 162–165
rapid, less-sophisticated
immunoassays 154–157, 163
screening immunoassays 151–157
serological screening 149–150, 159–160
specimen matrices for HIV screening 157
Western blot 151, 156, 157–159
specimen matrices for HIV screening 157
serological screening 149–150, 159–160
specimen matrices for HIV screening 157
hsital information system (HIS) 379–380
Hologic PANTHER 447
HSCT see hematopoietic stem-cell transplant
HLA see human leukocyte antigen
HME see human monocytic chlricosis
hMPV see human metapneumovirus
Hologic PANTHER 447
group information system (HIS) 379–380
HPLC see high performance liquid chromatography
HPV see human papillomaviruses
HRV see human rhinoviruses
HSCT see hematopoietic stem-cell transplant
HSIL see high-grade squamous intraepithelial lesions
HSV see herpes simplex virus
human bocavirus (HBoV) 400
human herpesviruses (HHV) 108–112
human immunodeficiency virus see HIV/AIDS
human leukocyte antigen (HLA) 154
human metapneumovirus (hMPV)
clinical manifestations 401
emerging infectious diseases 400–402
epidemiology 401
molecular tests 98–99
transmission and risk factors 400–401
treatment and prevention 402
human microbiome 459–460
human monocytic chlricosis (HME) 189
human papillomaviruses (HPV) 135–148
clinical manifestations 135–136
commercial systems 136–143
current challenges 143–144
cytology-based assays 136–137
future directions 144
genomics 135
genotyping 141–143
high-risk HPV and related infections 135–136
immunoassays 137–138
in situ hybridization 138
expression HPV and related infections 135
donucleic acid amplification tests 136–138
nucleic acid amplification tests 138–141
testing utility and recommendations 136
transmission and risk factors 135–136
human rhinoviruses (HRV) 98–99
HUS see hemolytic-uremic syndrome
hVISA see heterogeneous vancomycin intermediate S. aureus
hybrid-capture assays 138–140, 313
hybridization protection assay 48–49
ICD see immune complex dissociation
IFA see immunofluorescence assay; indirect fluorescence antibody
IFI see invasive fungal infections
IHC see immunohistochemistry
Illumigene C. difficile 81–82
Illumigene LAMP 447–448
Illumina MiSeq 453
IMC see immunohistochemistry (IHC)
immunoassays 142–143, 281
immunoassays 142–143, 281
immunofluorescence assay (IFA) antigen detection 354
automated immunoassay analyzers 319
clinical veterinary microbiology 354
diagnostic medical parasitology 294–297
HIV/AIDS 151, 159
identification of viruses 87, 92–93
mycoplasma 203–205
tick-borne diseases 185–186, 189
immunoglobulins
HIV/AIDS 151, 154, 156, 159–160
human papillomaviruses 142
identification and susceptibility testing of fungi 215–216, 220
mycoplasma 202–203, 205
tick-borne diseases 185–186
immunohistochemistry (IHC)
clinical veterinary microbiology 354–355, 364, 371
human papillomaviruses 137–138
tick-borne diseases 186, 189
India
antigen/antibody detection 516
Central Drugs Standards Control Organization 515–517
China 494–506
classification 1–2, 477, 484–485, 491, 494–495, 520–521, 525–526, 531–532
clinical efficiency/correlation studies 527
clinical performance 6–7
common issues with new FDA submissions 8–10
conformity assessments 485–486, 521, 524, 545
current microbiology device review regulatory pathways 2–4
definition of IVDs 477
de novo petitions 3
device description 5
documentation 477–478
European Directive 98/79/EC 507, 514, 520, 537, 545
Food and Drug Administration 1–2, 473, 486, 487
foreign manufacturers 527
France 507–514
historical development 1, 475
identification of viruses 88, 97, 100–103
implications of regulatory level authorities 514
in vitro diagnostic devices (cont’d)
inclusions and exclusions 545
India 515–519
intended use 5
Italy 520–524
Japan 525–530
Korea, Republic of 531–534
labeling 9
major elements of submission to the FDA 5–7
marketing approval 530
marketing licenses 526
Medical Device Amendment 1–2
Medical Devices Act (Korea) 531–532
Medicines and Healthcare Products Regulatory Agency 537, 545
MERCOSUR 476–477
National Association of Testing Authorities 486–487
National Health Insurance coverage 530
national IVDs 481
National Pathology Accreditation Advisory Council 486–487, 489
new and emerging pathogens and public health emergencies 9–10
new technologies 9
nucleic acid amplification tests 516–519
Pharmaceuticals and Medical Devices Agency 525–526, 530
premarket amendment/application 3–4, 7, 9
Premarket Notification 510(k) 2–3, 9
prevalence and predictive values 7–8
product certification 495, 527–529
product characteristics or dossier 478–481
RCPA quality assurance programs 486, 487
registration of manufacturers 524
registration procedure 494–496
registration requirements 477
sensitivity and specificity 7
South Africa 535–536
State Food and Drug Administration 494–496
Therapeutic Goods Administration 483–486, 489
United Kingdom 537–545
Ion Torrent Personal Genome Machine 453–454
IRB see Institutional Review Board
ISH see in situ hybridization
ISO see International Organization for Standardization
IsoAmp HSV Assay 109
Isolator 12–13
isothermal microcalorimetry (IMC) 429
Italy
commercial systems 522–523
conformity assessments 521, 524
European Directive 98/79/EC 520
in vitro diagnostic devices 520–524
national classification of medical devices 520–521
registration of manufacturers 524
regulatory requirements and product information 520–524
IUO see investigational use only
IVD see in vitro diagnostic devices
Ixodes spp. 190
Japan
classification of diagnostic reagents 525–526
clinical efficiency/correlation studies 527
foreign manufacturers 527
in vitro diagnostic devices 525–530
marketing approval 530
marketing licenses 526
National Health Insurance coverage 530
Pharmaceuticals and Medical Devices Agency 525–526, 530
product certification 527–529
regulatory requirements and product information 525–530
regulatory structure 525–526
Knot’s test 369–370
Korea, Republic of
classification of IVDs 531–532
commercial systems 532–533
in vitro diagnostic devices (IVD) 531–534
Medicines Devices Act 531–532
regulatory requirements and product information 531–534
laboratory-developed tests (LDT) 103–105, 108–109, 112–113
laboratory information systems (LIS) 377–385
analytical instruments 379
antimicrobial susceptibility testing 415
bandwagon effect 384
cases 383–384
categorization 377–378
commercial systems 381–382
criteria for comparison of current systems 382
historical development 380–382
infection control systems 382
interfaces and additional features 379–380
inventory management 379
management of LISs 384
modules of commercial LISs 380–382
personnel management and training 384–385
quality control management 379
reflexive action based on results 378–379
Report Module 379
Requests for Proposal 383–384
selecting an information system 383
software to support management of microbiology 378–380
specialized software 382–383
Laboratory Medicine Best Practices (LMBP) 460–462
Laboratory Response Network (LRN) 433, 435–436
LAMP see loop-mediated isothermal amplification
LAT see latex agglutination test
lateral flow assay (LFA) 216–217
latex agglutination test (LAT)
clinical veterinary microbiology 355, 361
identification and susceptibility testing of fungi 215–218
identification of anaerobic bacteria 75
tick-borne diseases 185–186
LCx see liquid-based cytology
LBRF see louse-borne relapsing fever
LCx see Mycobacterium tuberculosis assay 275
LDT see laboratory-developed tests
LEE see locus enterocyte effacement
Legionella spp. 45–46
Leishmania spp. 370
LFA see lateral flow assay
LGV see lymphogranuloma venereum
LightCycler SeptiFast Test MGRADE 240–241
Line Probe Assay (LiPA) 142–143, 280–282
lipopolysaccharide (LPS) 364
liquid-based cytology (LBC) 136–137
LIS see laboratory information systems
LMBP see Laboratory Medicine Best Practices
locus enterocyte effacement (LEE) 393
logical observation identifier names and codes (LOINC) 380, 382
loop-mediated isothermal amplification (LAMP)
emerging infectious diseases 387–388
future directions 447–448
molecular microbiology 311, 312
mycoplasma 208
louse-borne relapsing fever (LBRF) 397
lower respiratory infections (LRI) 97–98
low-grade squamous intraepithelial lesions (LSIL) 136–137
LPS see lipopolysaccharide
LRI see lower respiratory infections
LRN see Laboratory Response Network
LSIL see low-grade squamous intraepithelial lesions
Lucio phenomenon 398–400
Luminex Multicode-PLx/RTx 105
Luminex xTAG/xMAP 100, 102, 243, 445–446
Lyme disease 186–187
lymphogranuloma venereum (LGV) 179
magnetic resonance (MR) 457
malaria 305–307, 386–389
Malassezia pachydermatis 365
MALDI-ToF see matrix-assisted laser-desorption ionization time-of-flight
manual agar gradient diffusion method 423–424
manual blood cultures 11–13
identification and susceptibility testing of fungi 220–222
Isolator 12–13
Oxoid Signal 12
SEPTI-CHEK 11–12, 276
manual disk diffusion test 424
marketing approval 530
marketing licenses 526
mass spectrometry (MS)
 future directions 449–451
 identification of aerobic bacteria 21, 22, 49
 identification of anaerobic bacteria 71–73
 molecular microbiology 315
MAT see microscopic agglutination test
matrix-assisted laser-desorption ionization time-of-flight (MALDI-ToF)
antimicrobial susceptibility testing 428–429
clinical veterinary microbiology 359
 future directions 449–451
 identification and susceptibility testing of fungi 230–234, 240, 260–261
 identification of aerobic bacteria 21, 22, 43–44, 49
 identification of anaerobic bacteria 71–73
MALDI Biptyper 231–234, 449–450
 molecular microbiology 315
 susceptibility testing 260–261
MCC see Medicines Control Council medical countermeasures (MCM) 9–10
Medical Device Amendment (MDA) 1–2
Medical Devices Act (Korea) 531–532
Medical Devices Regulations 491–492
Medicare Australia 486
Medicines and Healthcare Products Regulatory Agency (MHRA) 537, 545
Medicines Control Council (MCC) 535
MERCOSUR 476–477
Meridian illumigene 36, 208, 211
Meridian ImmunoCard 205
merthiolate–iodine–formalin (MIF) 292
methicillin-resistant coagulase-negative Staphylococcus spp. (MR-CoNS) 427–428
methicillin-resistant S. aureus (MRSA)
antimicrobial susceptibility testing 418, 420–421, 425–428
 molecular typing 336, 337, 340
 rapid devices and instruments 33, 46–47
methicillin-susceptible S. aureus (MSSA) 47
MGIT see Mycobacterial Growth Indicator Tube
MHRA see Medicines and Healthcare Products Regulatory Agency
MIC see minimum inhibitory concentrations
microarray-based assays 314–315, 342
Microbial Identification System 236, 250
microbiological biorepositories 462
 microbiology laboratory information systems see laboratory information systems
Microgen systems 34, 37
MicroScan 22–26, 31–32, 38
AutoScan 4 system 422
Rapid Anaerobe Panel 66, 67–68
Rapid Yeast Identification panel 234–235
WalkAway plus system 416, 418–419
microscopic agglutination test (MAT) 364
MicroSEQ 500 16S rDNA Bacterial Identification System 279
Microsporum spp. 365–366
MiciSTREP plus panel 416, 419
MIDI Sherlock Microbial Identification System 29, 73
MIF see methanolite–iodine–formalin
minimum inhibitory concentrations (MIC) antimicrobial susceptibility testing 414–415, 417–425
identification and susceptibility testing of fungi 209–210, 249–252, 258–261
mycoplasma 209–210
MiniION system 453–454
MLST see multilocus sequence typing
modified polyvinyl alcohol (PVA) 293
molecular microbiology 309–318
amplicon detection and identification platforms 313–315
amplification methods and platforms 310–313
branched DNA 313
cleave/Invader technology 313
concepts and definitions 309
fluorescence resonance energy transfer 314
 future directions 316
helicase-dependent amplification 312
hybrid-capture assays 313
loop-mediated isothermal amplification 311, 312
mass spectrometry 315
microarray-based assays 314–315
nucleic acid sequence-based amplification 311, 312
peptide nucleic acid fluorescence in situ hybridization 314
polymerase chain reaction 309, 311–312, 314–316
 probe amplification methods 313
 sequencing 315
 signal amplification methods 313
 specimen processing and nucleic acid extraction platforms 309–310
 strand-displacement amplification 312
target amplification methods and platforms 311–312
transcription-mediated amplification 312
 molecular tests
assays for enteric viruses 106–107
assays for enterovirus and parechovirus 107–108
assays for transplantation monitoring 111–112
blood culture systems 18–19
commercial systems 100–109, 112
 concepts and definitions 97
detection of respiratory viruses 98–100
diagnostic medical parasitology 297–303
enteric viruses 105–107
enterovirus and parechovirus 107–108
genotyping 141–143
herpesviruses 97–99, 108–109
HIV/AIDS 161–162
 identification and susceptibility testing of fungi 236–248
identification of aerobic bacteria 21, 36, 45
identification of anaerobic bacteria 74–75, 81–82
identification of viruses 97–120
implementation and additional considerations 112–113
 in vitro diagnostic tests 97, 100–103
laboratory developed, investigational and research-use only tests 103–105
mycoplasma 206–211
nucleic acid amplification tests 97, 98–109, 113
pyrosequencing 244–245
 qualitative detection of herpesviruses 109
respiratory viral infections 97–105
tick-borne diseases 186
transplantation-associated viruses 109–112
viral hepatitis 130–131
see also polymerase chain reaction
molecular typing 336–345
comparative studies 340–343
 concepts and definitions 336–337
 microarray-based assays 342
multilocus sequence typing 336, 340–342
next generation sequencing 336, 342–343
pulsed-field gel electrophoresis 336, 337–338
repetitive element PCR 336, 337–340
ribotyping 336, 340
MR see magnetic resonance
MR-CoNS see methicillin-resistant coagulase-negative Staphylococcus spp.
MRSA see methicillin-resistant S. aureus
MS see mass spectrometry
MSSA see methicillin-susceptible S. aureus
Multicode RTx HSV 109
multilocus sequence typing (MLST) 336, 340–342
multiplex polymerase chain reaction (PCR) 357, 444–447
Mycobacterium
Mycobacterial Growth Indicator Tube
Mycoplasma
mycology
see M. tuberculosis 517–518
M. lepromatosis
M. leprae
NASBA
see Nasosphere Verigene 446–447
NAFTA
see North American Free Trade Agreement
MycAssay PCR kits 241–243
590
Index
FAST MYCOSCREEN/MYCO
microsoft excel
Microsoft Excel
2014
Mycobacteria 273–283
complement fixation 203
commercial systems 198–202, 203–209
cold agglutinins 202–203
identification 278–280
drug resistance 273, 274, 281
immunodiagnosis of tuberculosis 281
specimen processing 273
susceptibility testing 280–281
Myocobacterial Growth Indicator Tube (MGIT) 276–277
Mycobacterium spp. 17, 362–363
M. leprae 399–400
M. lepromatosis 398–400
M. tuberculosis 517–518
mycology see fungi
Mycoplasma IST kit 200
Mycoplasma spp. 195–213
antimicrobial susceptibility testing 209–210
clinical manifestations 195–196
clinical veterinary microbiology 362
cold agglutinins 202–203
commercial systems 198–202, 203–209
culture-based diagnosis 197–202
culture-based diagnosis 203–205
culture-based diagnosis 210–211
genital mycoplasma assays 205–206, 208–209
growth media and diagnostic kits 198–202
indicators for diagnostic testing 196–197
indirect immunofluorescence assay 203–205
molecular tests 206–211
mycoplasmas and ureaplasmas as human pathogens 195–196
nucleic acid amplification tests 206–211
particulate agglutination 203–205
polymerase chain reaction 195–197, 200, 205–211
serological tests 202–206
specimen collection and transport 198
specimens appropriate for culture 197–198
MYCOSCREEN/MYCOFAST’ 199–200
NAAT see nucleic acid amplification tests
NAFTA see North American Free Trade Agreement
Nasosphere Verigene 446–447
NASBA see nucleic acid sequence-based amplification
National Association of Testing Authorities (NATA) 486–487
National Health Insurance coverage 530
National Institute of Biologicals (NIB) 516
National Pathology Accreditation Advisory Council (NPAAC) 486–487, 489
National Veterinary Service Laboratories (NVSL) 348, 351–355
negative-strand polymerase chain reaction (PCR) 357
Neisseria spp. 2, 45
N. gonorrhoeae 178, 180–182
neonates 159–160, 178–179
Neo-Sensitas tablet diffusion assay 257–258
Neospora caninum 370
nested polymerase chain reaction (PCR) 357
newly emerging tick-borne disease 191
next generation sequencing (NGS) 315, 336, 342–343, 452–458
NIB see National Institute of Biologicals
noroviruses 94–95, 105–107
North American Free Trade Agreement (NAFTA) 491
not substantially equivalent (NSE) 3, 4
novel phlebovirus 191
NSE see not substantially equivalent
nucleic acid amplification tests (NAAT) 309–310
amplification and identification platforms 313–315
amplification methods and platforms 310–313
Chlamydia trachomatis 175–182
future directions 447–448
HIV/AIDS 149, 151–152
human papillomaviruses 138–141
identification of aerobic bacteria 47–48
identification of viruses 97, 98–109, 113
in vitro diagnostic devices 487–489, 517–519
mycoplasma 206–211
specimen processing and nucleic acid extraction platforms 309–310
viral hepatitis 129–130
see also polymerase chain reaction nucleic acid extraction 309–310, 438–441
nucleic acid sequence-based amplification (NASBA) 311, 312
nucleic acid sequencing see sequencing
NVSL see National Veterinary Service Laboratories
Occupational Safety and Health Administration (OSHA) 436
off-label testing 143
OncoTect E6/E7 mRNA assay 141
One Health Initiative 346
optical mapping 454–455
OraQuick HCV Rapid Antibody Test 130
OraQuick In-Home HIV Test 156–157
OSHA see Occupational Safety and Health Administration
ova and parasite examination 294, 297–303
Oxoid Signal 12
p24 antigen 149–151, 153–155, 157, 160–161
PA see particulate agglutination
Pan American Health Organization (PAHO) 476
Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPR) 9–10
pandemic H1N1 influenza 391–393
Papillocheck HPV-screening 142–143
parainfluenza virus (PIV) 98–99
parasitology see diagnostic medical parasitology; individual species
parechovirus (PeV) 107–108
particulate agglutination (PA) 203–205
PCR see polymerase chain reaction
pelvic inflammatory disease (PID) 178
peptide nucleic acid fluorescence in situ hybridization (PNA-FISH)
future directions 448
identification and susceptibility testing of fungi 237–239
identification of aerobic bacteria 47
molecular microbiology 314
PeV see parechovirus
PFGE see pulsed-field gel electrophoresis
Pharmaceticals and Medical Devices Agency (PMDA) 525–526, 530
PHDS see Public Health Disease Surveillance
phenotypic testing
antimicrobial susceptibility testing 425–427
HIV/AIDS 165–167
identification of aerobic bacteria 21, 22–29
identification of anaerobic bacteria 61
PHL see public health laboratory
phylogenetic analysis 191
PID see pelvic inflammatory disease
PIV see parainfluenza virus
PJ see Pneumocystis jirovecii pneumonia
plaque-reduction neutralization test (PRNT) 190
Plasmodium spp. 305–307
P. knowlesi
clinical manifestations 387
emerging infectious diseases 386–389
epidemiology 386–387
transmission and risk factors 387
treatment and prevention 389
plate readers 423
pleuropneumonia-like organisms (PPLO) medium 199
PMA see premarket amendment
PMDA see Pharmaceuticals and Medical Devices Agency
PMNL see polymorphonuclear cells
PNA-FISH see peptide nucleic acid fluorescence in situ hybridization
Pseudomonas aeruginosa 15, 17
Public Health Disease Surveillance (PHDS) 382–383
public health laboratory (PHL) 380, 382
pulsed-field gel electrophoresis (PFGE) 336, 337–338
PVA see polyvinyl alcohol
pyrosequencing 244–245, 315, 451–452
Qiagen PyroMark Q24 452
Qiagen QIA symphony SP system 440
QuickFISH 239
QuickVue Influenza A+B 90
Quidel DHL 92–93
Quidel Sofia Influenza A & B 90–91
RATD see rapid antigen detection tests
Raman spectroscopy 457–458
random amplified polymorphic DNA (RAPD) 336
RAPD see random amplified polymorphic DNA
RapidID ANA II 65–67
rapid antigen detection tests (RATD) 87, 89–90, 92, 98
rapid devices and instruments
aerobic Gram-negative organisms 38–46
aerobic Gram-positive bacilli 37–38
aerobic Gram-positive cocci 29–37
antigen detection 75–81, 82, 87, 89–90, 92
automated systems 22–29, 38–40
Bacillus spp. 37–38
Bacteroides spp. 56–57, 65, 68–69
bioterrorism 436
blood culture systems 46–48
Bordetella spp. 44–45
Campylobacter spp. 42–43
clinical considerations 56–57
clinical veterinary microbiology 361–363
Clostridium spp. 56–59, 67–69, 73–82
collection, transport and storage of specimens 58–59
commercial systems 22–42, 46–49, 59–60, 64–71, 74, 77–82, 90–95
concepts and definitions 21, 56–57
Corynebacterium spp. 37–38
currently available technologies 21–29
cytomegalovirus 93–94
cytotoxicity testing 74–81, 82
detection and identification of viruses 87–96
diagnosis of anaerobic bacterial infections 57–64
diagnostic medical parasitology 294, 305–307
direct fluorescent antibody testing 44–45
direct fluorescent testing 44–45
diagnostic medical parasitology 294, 305–307
direct fluorescent antibody testing 44–45
diagnostic medical parasitology 294, 305–307
direct fluorescent testing 44–45
Emerging Technologies 49
Escherichia coli and Shiga Toxin 40–43
fastidious Gram-negative organisms 44–46
fatty acid analysis with gas chromatography 22
Fusobacterium spp. 65, 67
gas chromatography 73
gastrointestinal viruses 94–95
gene sequencing 71
glutamate dehydrogenase tests 74, 75–78, 82
Haemophilus and Neisseria spp. 45
Helicobacter spp. 43–44
herpes simplex virus 93–94
HIV/AIDS 154–157, 163
identification and susceptibility testing of fungi 226–236
identification of aerobic bacteria 21–55
identification of anaerobic bacteria 56–86
identification of unique enzymes 226–229
identification of yeasts and yeast-like organisms 229–236
immunodiagnostic tests 74–81
immunofluorescence staining of respiratory viruses 87, 92–93
incubation, inspection and subculture of colonies 59–60
influenza viruses 87, 88–93
interpretation of anaerobe identification results 70–71
 Legionella spp. 45–46
MALDI-ToF/MS 21, 22, 43–44, 49, 71–73
manual systems 37, 38
molecular tests 21, 36, 45, 74–75, 81–82
PCR-ESI/MS 73
peptide-nucleic acid fluorescent in situ hybridization 47
phenotypic testing 21, 22–29, 61
Porphyromonas spp. 65, 67, 73–74
preparation of inocula 65–67
presumptive identification and characterization of anaerobes 60–63
Prevotella spp. 65, 67, 73
protein mass spectrometry 22
respiratory syncytial virus 87, 91–93
rapid devices and instruments (cont’d)
Staphylococcus spp., 31, 32–36, 46–48
Streptococcus spp. 34–37
varicella zoster virus 93–94
Vibrio and Aeromonas spp. 44
rapid diagnostic tests (RDT) 305–307, 388, 392
Rapid ID 32 A 66, 68
rapidly growing mycobacteria (RGM) 275, 281
RapID systems 34, 37, 229–230
rapid trehalose 227
RAV see resistance-associated variants
RCPA see Royal College of Pathologists of Australasia
RDT see rapid diagnostic tests
real-time polymerase chain reaction (PCR) 357, 438, 441–443
Remel Microbiology Products 273–274
repetitive element PCR (rep-PCR) 336, 337–340
Report Module 379
rep-PCR see repetitive element PCR
Republic of Korea see Korea, Republic of
Requests for Proposal (RFP) 383–384
research-use only (RUO) tests
human papillomaviruses 142–143
identification of viruses 103–105, 112–113
mycoplasma 206
resistance-associated variants (RAV) 126
RESOLUTION Microbial Genotyping System 343
respiratory syncytial virus (RSV)
emerging infectious diseases 400–402
molecular tests 98
rapid devices and instruments 87, 91–93
respiratory tract infections (RTI) 97–98
respiratory viral infections 87–93, 97–105
restriction fragment length polymorphism (RFLP) 336, 358–359
reverse hybridization (RH) probe assay
human papillomaviruses 143
reverse-transcriptase polymerase chain reaction (RT-PCR)
clinical veterinary microbiology 356–357
emerging infectious diseases 392, 401–404
future directions 438, 441–447
identification of viruses 90–91, 100, 105–107, 109
mycoplasma 205, 209
tick-borne diseases 190–191
RFLP see restriction fragment length polymorphism
RFP see Requests for Proposal
RGM see rapidly growing mycobacteria
RH see reverse hybridization
Rhipicephalus spp. 185
ribotyping 336, 340
Rickettsia spp.
clinical manifestations 397, 398
emerging infectious diseases 397–398
epidemiology 397–398
tick-borne diseases 184–186
transmission and risk factors 397–398
treatment and prevention 398
RMSF see Rocky Mountain spotted fever
Roche Amplicor HPV test 140
Roche COBAS system 141–142, 181–182, 440
Roche GS Junior system 452
Roche Linear Array HPV genotyping test 142
Rocky Mountain spotted fever (RMSF) 185, 397–398
rotaviruses 94–95, 105–107
Royal College of Pathologists of Australasia (RCPA) 486, 487
RSV see respiratory syncytial virus
RTI see respiratory tract infections
RT-PCR see reverse-transcriptase polymerase chain reaction
SAF see sodium acetate–acetic acid–formalin
SAHPRA see South African Health Products Regulatory Authority
SALDA see Southern African Laboratory Diagnostics Association
Salmonella spp. 360, 434
SAMED see South African Medical Device Industry Association
sapoviruses 105–107
SARS see severe acute respiratory syndrome
Schaudinn’s fluid 292–293
SDA see strand-displacement amplification
sedimentation techniques 297, 300
SMA see single-molecule sequencing
sensitivity
clinical veterinary microbiology 349–350
Food and Drug Administration 7
molecular tests 113
SepsisTest 243–244
SEPTI-CHEK 11–12, 276
SeptiFast Test MGRADE 240–241
sequencing
capillary sequencing 451
clinical veterinary microbiology 359
high throughput sequencing 452–458
identification of anaerobic bacteria 71
molecular microbiology 315
molecular typing 336, 342–343
mycoplasma 281
next generation sequencing 315, 336, 342–343, 452–458
pyrosequencing 244–245, 315, 451–452
serological tests
clinical veterinary microbiology 364, 369–370
commercial serological assay formats 203–204
HIV/AIDS 149–150, 159–160
identification and classification 2
in vitro diagnostic devices (IVD) 516–517
mycoplasma 202–206
tick-borne diseases 185–191
viral hepatitis 127–129, 131
see also individual tests
SERS see surface enhanced Raman spectroscopy
serum 215–219
serum virus neutralization (SVN) 351
severe acute respiratory syndrome (SARS) 97, 386
severe fever with thrombocytopenia syndrome (SFTS) 402–403
SFDA see State Food and Drug Administration
SFTS see severe fever with thrombocytopenia syndrome
Sherlock 29, 73
Shiga Toxin 40–43, 393–394
Shigella dysenteriae 434
short read pyrosequencing 244–245, 315, 451–452
short turnaround time (STAT) requests 285
Simplexa assays 443, 444
single-molecule sequencing (SMA) 455–456
single-vial collection systems 293
SIRSCAN 2000 System 425
SMA see single-molecule sequencing
sodium acetate–acetic acid–formalin (SAF) 292
Sofia Influenza A & B 90–91
South Africa 535–536
South African Health Products Regulatory Authority (SAHPRA) 535–536
South African Medical Device Industry Association (SAMED) 536
Southern African Laboratory Diagnostics Association (SALDA) 536
Southern blot hybridization 355
specificity
clinical veterinary microbiology 349–350
Food and Drug Administration 7
molecular tests 113
spirochetes and spiral organisms 364
Staphylococcus spp.
antimicrobial susceptibility testing 417–421
blood culture systems 15, 17–18
clinical veterinary microbiology 361
rapid devices and instruments 31, 32–36, 46–48
STAT see short turnaround time
State Food and Drug Administration
(SFDA) 494–496
statistics 101 for developers 7–8
stand-displacement amplification
(SDA) 181–182, 312
Streptococcus spp.
antimicrobial susceptibility
testing 417–421
blood culture systems 16
clinical veterinary microbiology 361
rapid devices and instruments 34–37
Strongyloides stercoralis 368
study population 6
SurePath liquid-based Pap test 137
surface enhanced Raman spectroscopy
SurePath liquid-based Pap test 137
study population 6
StrainSpecific (SS) 360
Salmonella enterica subsp.
enterica serovar Typhi 405
transmission and risk factors 184, 186–191
tularemia 187–188
viral agents 189–190
tick-borne relapsing fever (TBRF) 187
TLA see total laboratory automation
TMA see transcription-mediated amplification
total laboratory automation (TLA) 458–459
Toxoplasma gondii 370
transcription-mediated amplification
(TMA)
Chlamydia trachomatis 181–182
future directions 447
molecular microbiology 312
mycobacteria 274
transplantation-associated viruses 109–112, 401–402
Trichinella spiralis 370
Trichomonas vaginalis 295–297, 303
Trichophyton spp. 241, 365–366
Trichomonas foetus 370–371
TRTV see turkey rhinotracheitis virus
Trypanosoma cruzi 370
TT see tuberculosis type leprosy
tuberculoid type leprosy (TT) 398
tuberculosis 517–518
tularemia 187–188
turkey rhinotracheitis virus (TRTV) 400
UMD see Universal Microbe Detection
United Kingdom
commmercial systems 538–544
conformity assessments 545
European Directive 98/79/EC 537, 545
inclusions and exclusions 545
in vitro diagnostic devices 537–545
Medicines and Healthcare Products
Regulatory Agency 537, 545
regulatory requirements and product
information 537–545
United States of America see Food and Drug Administration
universal fixative 293
Universal Microbe Detection (UMD)
systems 243–244
Uni-Yeast-Tek 229
upper respiratory infections (URI) 97–98
Ureaplasma spp.
antimicrobial susceptibility
testing 209–210
commercial molecular assays 208–209
culture-based diagnosis 197–199
future directions 210–211
growth media and diagnostic
kits 198–199
indications for diagnostic
testing 196–197
mycoplasmas and ureaplasmas as human
pathogens 195–196
specimen collection and transport 198
specimens appropriate for
culture 197–198
URI see upper respiratory infections
US FDA see Food and Drug Administration
vaccines 123–124, 126–127, 143–144
vancomycin intermediate S. aureus
(VISA) 430
vancomycin-resistant Enterococcus
(VRE) 425–426
varicella zoster virus (VZV) 93–94, 108–109
Verigene systems 47–48, 102, 106–107, 428
VersaTREK 17–18, 222, 224, 277–278, 280–281
veterinary microbiology see clinical
veterinary microbiology
VI see virus isolation
vibrating cantilevers 429
Vibrio spp. 44
VIDAS system 78–79
viral hepatitis see hepatitis
Virginia Polytechnic Institute (VPI)
system 61
virology
antigen detection 87, 89–90, 92
assays for enteric viruses 106–107
assays for enterovirus and
parvovirus 107–108
clinical veterinary microbiology 350–351
commercial systems 90–95
detection of respiratory viruses 98–100
emerging infectious diseases 400–404
enteric viruses 105–107
enterovirus and parvovirus 107–108
enzyme immunoassay 87
gastrointestinal viruses 94–95
immunofluorescence staining of
respiratory viruses 87, 92–93
influenza viruses 87, 88–93, 98, 100
molecular tests 97–120
qualitative detection of herpesviruses 109
rapid devices and instruments 87–96
respiratory viral infections 87–93, 97–105
transplantation-associated
viruses 109–112
see also individual species
virus isolation (VI) 350–351
VISA see vancomycin intermediate S. aureus
Vitek 2 system 66–67, 258–260, 416–418
Vitek 28–29, 31, 39–40, 45
Vitek MS/MS MALDI-TOF 234, 450–451
Vitek YBC/Vitek 2 YST 227–228, 235–236
VPI see Virginia Polytechnic Institute  
VRE see vancomycin-resistant Enterococcus  
VTEC-Screen Seiken RPLA 42  
VYOO system 246  
VZV see varicella zoster virus  

Wadsworth-KTL Anaerobic Bacteriology Manual 61, 63  
Walk-Away Specimen Processor (WASP) 458–459  
Wampole Isolator System 220–222  
WASP see Walk-Away Specimen Processor  
WEE-TABS system 63–64  
Western blot automated immunoassay analyzers 319  
clinical veterinary microbiology 353  
HIV/AIDS 151, 156, 157–159  
WGS see whole genome sequencing  
WHO see World Health Organization  
whole genome sequencing (WGS) 343, 454–455, 461  
World Health Organization (WHO) 389, 391, 476  
XDR see extremely drug resistant  
xTAG gastrointestinal pathogen panel 106  
Zika virus (ZIKV) 403–404  
zoonotic pathogens 346–347, 364