Anexa nr. 7
la Documentaţia standard nr.____
din "___" _____ 20__

CERERE DE PARTICIPARE

Către CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr ocds-b3wdp1-MD-1697110563214 din 12/10/2023, privind aplicarea procedurii pentru atribuirea contractului privind ***Achiziționarea testelor și consumabilelor întru realizarea Programului Naţional de combaterea hepatitelor virale B, C și D pentru anul 2024***, noi Medist Grup SRL, am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării 23.11.2023

Digitally signed by Anghel Gabriela-Cristina
Date: 2023.11.23 10:52:58 EET
Reason: MoldSign Signature
Location: Moldova

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

ORDIN DE PLATA NR.469 Tip.doc. 1

DATA EMITERII: 22 noiembrie 2023

PLATITI:94787-52 LEI: Nouazeci si Patru Mii Sapte Sute Optzeci si Sapte, 52

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI022242600000269MDL
CODUL FISCAL:1018600004516

PRESTATORUL PLATITOR
B.C VictoriaBank S.A. s.26 Chisinau

BENEFICIAR:(R) CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE CODUL IBAN:MD23TRPCCC518430B01859AA
CODUL FISCAL:1016601000212

PRESTATORUL BENEFICIAR
Min.Finantelor-Trezoreria de Stat

DESTINATIA PLATII: /P102/94787,52 Garantia oferta 2 procente, pentru LP nr. 21102456 din12.10.2023

NORMAL/URGENT:NO

L.S.

CODUL TRANZACTIEI:101

DATA PRIMIRII: _____

DATA EXECUTARII: _____

SEMNATURILE EMITENTULUI

_____
SEMNATURA PRESTATORULUI

«VICTORIABANK»
DIRECȚIA OPERAȚIUNI
22. NOI. 2023

MOTIVUL REFUZULUI L.S.

10:56:29 22 NOV 2023
Semnatura electronica:
RrGH/eFWunduLu578z+wxj8qCnQtua2DxiKy7/Dip/Ck+5JygmznVQnQSR0wfI7XT++dEbA+Urw4
H4/jjvbof4/Q7bGNHagnOP7WIlkmh48vGpyQQtz5vj9qTZ29PrgOFQzD4+ZICyqeP9yu8gmlxklt
oRxeCwqvQp8PWNuyuqlIY+CML3jtUU/cWfK/3xE2rQZuuik8ElvpzwnZc1037XJ3aTNVkNiV2GJj
nVfpdodA/tHhgn6kDcwiE0Prg4mEwsrtzhoAW3xRsf79ygVA+aUaVtWkOarjd27fONveqiHT8E2a
8KtC9vE+L/OMeE9yJGwjU1ck0nBuebfP7/A99Q==

I.P. "AGENȚIA SERVICII PUBLICE"
Departamentul înregistrare și licențiere a unităților de drept

Extras
din Registrul de stat al persoanelor juridice
nr. **117493** din **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "MEDIST GRUP"**
Denumirea prescurtată: **"MEDIST GRUP" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată**
Numărul de identificare de stat și codul fiscal: **1018600004516**
Data înregistrării de stat: **02.02.2018**
Sediu: **MD-2012, strada Mitropolit Gavriil Bănulescu-Bodoni 25, ap. 33, mun. Chişinău, Republica Moldova**
Genurile de activitate:

1. **Comerţ cu ridicata al produselor farmaceutice;**
2. **Comerţ cu ridicata nespecializat;**
3. **Repararea echipamentelor electronice şi optice;**
4. **Activităţi de testare şi analize tehnice;**
5. **Comerţ cu amănuntul al articolelor medicale şi ortopedice, în magazine specializate;**

Capitalul social: **373026 Lei**
Administrator: **ANGHEL GABRIELA-CRISTINA IDNP 2017803985939**
Asociați:

1. **MEDIST IMAGING & P.O.C. S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
2. **MEDIST LIFE SCIENCE S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
3. **MEDIST S.R.L., partea socială 6433 Euro, ce constituie 34.00%**

Beneficiari efectivi: **MANOLE IONEL, KLUMPNER CATALINA ANA, VLĂDESCU CARMEN, VLĂDESCU SEBASTIAN-ALEXANDRU**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de 15.09.2023

Specialist coordonator
Marina Franţuz
tel. 022-207837

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI ANTREPRENORULUI

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. №: 0853516

Din От: 22.11.2023

1 DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare
Фискальный код/Идентификационный номер

1018600004516

Denumirea
Наименование

MEDIST GRUP S.R.L.

2 ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT/ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ НЕДОИМКИ СОГЛАСНО ДАННЫХ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

0,00 **lei**/лей

3 VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО

07.12.2023

Prezentul certificat este eliberat în temeiul Art. 131, alin. (5^3) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5^3) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (https://mcabinet.gov.md) la 22.11.2023 08:53:13

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /
Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA

www.victoriabank.md

Filiala nr. 26 Chișinău
str. Mt. Bănulescu-Bodoni, 28/1
MD-2005, mun. Chișinău
Tel.: (+373 22) 92-92-52
Fax: (+373 22) 78-47-30
SWIFT: VICBMD2X469
IDNO 1002600001338
Capital social – 250 000 910 lei
www.victoriabank.md

Nr. 261466 din "19" iunie 2018

La Nr. 395 din "19" iunie 2018

Secret bancar
Confidențial

CERTIFICAT

Prin prezentul, BC "VICTORIABANK" SA Sucursala nr.26 Chişinău, codul băncii VICBMD2X469, cod fiscal 1002600001338, confirmă că MEDIST GRUP SRL, cod fiscal 1018600004516, deţine următoarele conturi curente în format IBAN:

MD57VI022242600000269MDL;
MD76VI022242600000105USD;
MD61VI022242600000116EUR;
MD83VI022242600000008RON.

Certificatul este eliberat la cererea clientului pentru a fi prezentat la destinaţie.

Cebanu Valentina
Director

REPUBLICA MOLDOVA, mun. CHIȘINĂU
SUCURSALA Nr.26 CHIȘINĂU
Nr. 1002600001338
BANCA COMERCIALĂ "VICTORIABANK" S.A.

Blanovscaia Anna
Contabil-şef

Ex: Scutaru Lilia
tel. 022 78-47-32

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

Entitatea: MEDIST GRUP S.R.L.
Cod CUIÎO: 41247072
Cod IDNO: 1018600004516

Sediul:
MD: 2012
Raionul(municipiul): 105, DDF BUIUCANI
Cod CUATM: 0120, SEC.BUIUCANI
Strada: Mitropolit Gavriil Banulescu-Bodoni nr.25 of.33

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 23, Proprietatea statelor străine
Forma organizatorico-juridică: 530, Societăţi cu răspundere limitată

Date de contact:
Telefon: 068681147
WEB: www.medist.md
E-mail: natalia.mutu@medist.md
Numele și coordonatele al contabilului-șef: Dl (dna) Natalia Mutu Tel. 068681147

Numărul mediu al salariaților în perioada de gestiune: 6 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Anghel Gabriela-Cristina

Unitatea de măsură: leu

BILANŢUL

Anexa 1

la 31.12.2022

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	**ACTIVE IMOBILIZATE** **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		

	2. Terenuri	070		
	3. Mijloace fixe, total	080	1673086	3028298
	din care: 3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	1657741	3018214
	3.4. mijloace de transport	084		
	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	15345	10084
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120	141992	141992
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	1815078	3170290
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	1815078	3170290
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	32816	31649
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	2084205	852838
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	2117021	884487

	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	745255	3969789
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	192050	982652
	4. Creanțele ale personalului	330		856
	5. Alte creanțe curente	340	2484163	1093188
	6. Cheltuieli anticipate curente	350	13622	48056
	7. Alte active circulante	360	12373	
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	3447463	6094541
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	3083838	4161583
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	8648322	11140611
	TOTAL ACTIVE (rd.230 + rd.420)	430	10463400	14310901
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	373026	373026
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	373026	373026
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor	560	4576184	4576184

	precedenți			
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	826229
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	4576184	5402413
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	4949210	5775439
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	2293001	1579325
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643	2293001	1579325
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700	2293001	1579325
E.	**DATORII CURENTE**			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720	1965429	1344767
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723	1965429	1344767
	3. Datorii comerciale curente	730	22996	2165195
	4. Datorii față de părțile afiliate curente	740	15427	3446175
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	479003	
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	738334	
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	3221189	6956137
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		

	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	10463400	14310901

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2022 pînă la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	33578934	29021092
din care: venituri din vînzarea produselor și mărfurilor	011	33233405	28497093
venituri din prestarea serviciilor și executarea lucrărilor	012	93698	126338
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanţare	015		
alte venituri din vînzări	016	251831	397661
Costul vînzărilor, total	020	21572504	20867803
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	21572504	20867803
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanţare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	12006430	8153289
Alte venituri din activitatea operațională	040	34729	135089
Cheltuieli de distribuire	050	309807	118118
Cheltuieli administrative	060	3316071	4920088
Alte cheltuieli din activitatea operațională	070	430627	1931079
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	7984654	1319093
Venituri financiare, total	090	1154867	786797
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		

venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	1154867	786797
Cheltuieli financiare, total	100	685067	904528
din care: cheltuieli privind dobînzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	685067	904528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	469800	-117731
Venituri cu active imobilizate și excepționale	120		5290
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		5290
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	469800	-112441
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	8454454	1206652
Cheltuieli privind impozitul pe venit	170	738805	380423
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7715649	826229

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2022 pînă la 31.12.2022

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010	373026			373026
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	373026			373026
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere	130	4576184			4576184

	neacoperită) al anilor precedenți					
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	826229		826229
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	4576184	826229		5402413
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	4949210	826229		5775439

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2022 pînă la 31.12.2022

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	36964792	29053578
Plăți pentru stocuri și servicii procurate	020	31765229	20406745
Plăți către angajați și organe de asigurare socială și medicală	030	1675720	2732087
Dobînzi plătite	040		
Plata impozitului pe venit	050		1868681
Alte încasări	060		5290
Alte plăți	070	490294	1588647
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	3033549	2462708
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	2042210	
Plăți aferente rambursării creditelor și împrumuturilor	160	2474672	1457991
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-432462	-1457991
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	2601087	1004717
Diferențe de curs valutar favorabile (nefavorabile)	220	67584	73028

Sold de numerar la începutul perioadei de gestiune	230	415167	3083838
Sold de numerar la sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	3083838	4161583

Documente atașate - Notă explicativă (fișierul pdf)

Versiune de imprimare
Salvare

Recipisa 2

Respondent
Codul fiscal: 1018600004516, denumire: MEDIST GRUP S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2022
Data prezentarii: 25.05.2023
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 25.05.2023 16:56:13

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs.
Urmează verificarea şi validarea raportului de către specialistul BNS pe domeniu.

DECLARAŢIE
privind valabilitatea ofertei

Către: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, **privind** ***Achiziționarea testelor și consumabilelor întru realizarea Programului Naţional de combaterea hepatitelor virale B, C și D pentru anul 2024*****,** pentru o durată de 160 zile, (una sută șase zeci), respectiv până la data de 30/05/2024 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 23.11.2023

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

MEDIST Grup

Soluții pentru sănătate

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, Oficiul 33, declar pe propria răspundere că:

- mostrele (2 bucăți) vor fi prezentate în termen de 10 zile de la solicitare, ambalate și etichetate cu specificare obligatorie a modelului articolului, producătorului și țării de origine pe ambalajul original al mostrei. Mostrele vor fi prezentate în termen de 10 zile de la solicitare, într-o cutie pe care se va indica denumirea operatorului economic și numărul procedurii de achiziție publică. Se va prezenta lista mostrelor incluse în cutie și numărul de lot al acestora cu scrisoare de însoțire semnată. Pe fiecare produs în parte va fi indicat numărul lotului și denumirea operatorului economic.
- termenul de valabilitate restant la livrare va constitui nu mai puțin de 80% din termenul total al produsului.
- livrarea produselor la destinatar se va efectua cu respectarea condițiilor de păstrare și transportare pe tot parcursul lanțului de transportare de la fabricant la beneficiar.
- bunurile ce urmează a fi achiziționate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale, mai jos dovada:

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						cepheid	medist		
DM000221904	TEST PENTRU DETERMINAREA HEPATITEI C	XPERT®	HCV VIRAL LOAD	GXHCV-VL-CE-10	Suedia	CEPHEID AB	MEDIST GRUP S.R.L.	Rg04-000173	23-07-2019
DM000221903	TEST PENTRU DETERMINAREA HEPATITEI B	XPERT®	HBV VIRAL LOAD	GXHBV-VL-CE-10	Suedia	CEPHEID AB	MEDIST GRUP S.R.L.	Rg04-000173	23-07-2019
DM000204993	TEST DE CALIBRARE PENTRU SISTEM AUTOMAT DE DIAGNOSTIC MOLECULAR	Xpert®	Check	XPERTCHECK-CE-5	SUA	CEPHEID	MEDIST GRUP S.R.L.	A07.PS-01.Rg04-91	05-04-2019

Data completării 23.11.2023

Cu stimă,

Ofertant/candidat

Gabriela-Cristina Anghel

(semnătura autorizată)

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
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BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HCV Viral Load
Catalogue number(s): GXHCV-VL-IN-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A
Conformity Assessment route: Annex IV
Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797
EC Certificate – Full Quality Assurance: CE 708525
EC Design-Examination Certificate: CE 708527

Signed on behalf of Cepheid AB by:

Lena Kirsel — May 23, 2022

Signature — Date of Issue

Lena Kirsel
Senior Manager of Regulatory Affairs

Place of Issue: Solna, Sweden

Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HBV Viral Load
Catalogue number(s): GXHBV-VL-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A
Conformity Assessment route: Annex IV
Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797
EC Certificate – Full Quality Assurance: CE 708525
EC Design-Examination Certificate: CE 708526

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

May 23, 2022
Date of Issue

Place of Issue: Solna, Sweden

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cepheid
904 Caribbean Drive
Sunnyvale
California
94089
USA

Holds Certificate Number: **MD 774674**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Service, Installation, Distribution and Refurbishment of Analyzers, Control of Manufacture of Analyzers used for Monitoring and Patient Management.
Transfer from: LRQA Limited
Certificate identity number: 10454286

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-08-02
Latest Revision Date: 2022-08-02

Effective Date: 2022-08-02
Expiry Date: 2024-12-18

...making excellence a habit.™

Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 904 Caribbean Drive Sunnyvale California 94089 USA	Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Service, Installation, Distribution and Refurbishment of Analyzers, Control of Manufacture of Analyzers used for Monitoring and Patient Management.
Cepheid 632 Caribbean Drive Sunnyvale California 94089 USA	Distribution of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1339 Moffet Park Drive Sunnyvale California 94089 USA	Service and Support, General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1327 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1315 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 918 Caribbean Drive Sunnyvale California 94089 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.

Original Registration Date: 2022-08-02

Effective Date: 2022-08-02

Latest Revision Date: 2022-08-02

Expiry Date: 2024-12-18

Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 1324 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development, Purchasing, General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 7000 Gateway Blvd. Newark California 94560 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 6601 Overlake Pl. Newark California 94560 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 44509 Pacific Commons Blvd. Fremont California 94538 USA	Distribution of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management.
Cepheid Mätarvägen 45 196 37 Kungsängen Sweden	Distribution of in-vitro Diagnostics used for Monitoring and Patient Management.
Cepheid 225 North Guild Avenue Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management

Original Registration Date: 2022-08-02

Effective Date: 2022-08-02

Latest Revision Date: 2022-08-02

Expiry Date: 2024-12-18

Certificate No: **MD 774674**

Location	Registered Activities
Cepheid 121 N Guild Ave. Lodi California 95240 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 850 East Thurman Road Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management

Original Registration Date: 2022-08-02
Effective Date: 2022-08-02
Latest Revision Date: 2022-08-02
Expiry Date: 2024-12-18

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 708525**

Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

In respect of:

Design and manufacture of nucleic acid amplification tests for the quantitative detection of HIV-1, Hepatitis B (HBV), Hepatitis C (HCV) and qualitative detection of HIV-1 and Chlamydia Trachomatis infections

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-03-28** Date: **2020-02-11** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance

Supplementary Information to CE 708525

Issued To:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Number	Device Name	Intended purpose per IFU
Annex II List B		
IVD 0305	Xpert CT	Qualitative in vitro real-time PCR test for the automated detection and differentiation of genomic DNA from Chlamydia trachomatis (CT) to aid in the diagnosis of chlamydial urogenital disease.
IVD 0305	Xpert CT/NG	Qualitative in vitro real-time PCR test for the automated detection and differentiation of genomic DNA from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) to aid in the diagnosis of chlamydial and gonorrhoeal urogenital disease.
IVD 0305	Xpert CT/NG	Qualitative in vitro real-time PCR test for the automated detection and differentiation of genomic DNA from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) to aid in the diagnosis of chlamydial and gonorrhoeal disease in the urogenital tract and extragenital sites (pharynx and rectum).
Annex II List A		
IVD 0203	Xpert HBV Viral Load	See CE 708526
IVD 0203	Xpert HCV Viral Load	See CE 708527
IVD 0203	Xpert HCV VL Fingerstick	See CE 708531
IVD 0201	Xpert HIV-1 Qual	See CE 708533
IVD 0201	Xpert HIV-1 Viral Load	See CE 708535

First Issued: **2019-03-28** Date: **2020-02-11** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 708525**
Date:	**2020-02-11**
Issued To:	**Cepheid AB** **Röntgenvägen 5** **SE-171 54 Solna** **Sweden**

Subcontractor:	**Service(s) supplied**
Cepheid 904 Caribbean Drive Sunnyvale California 94089 USA	**Design** **Manufacture**

...making excellence a habit.™

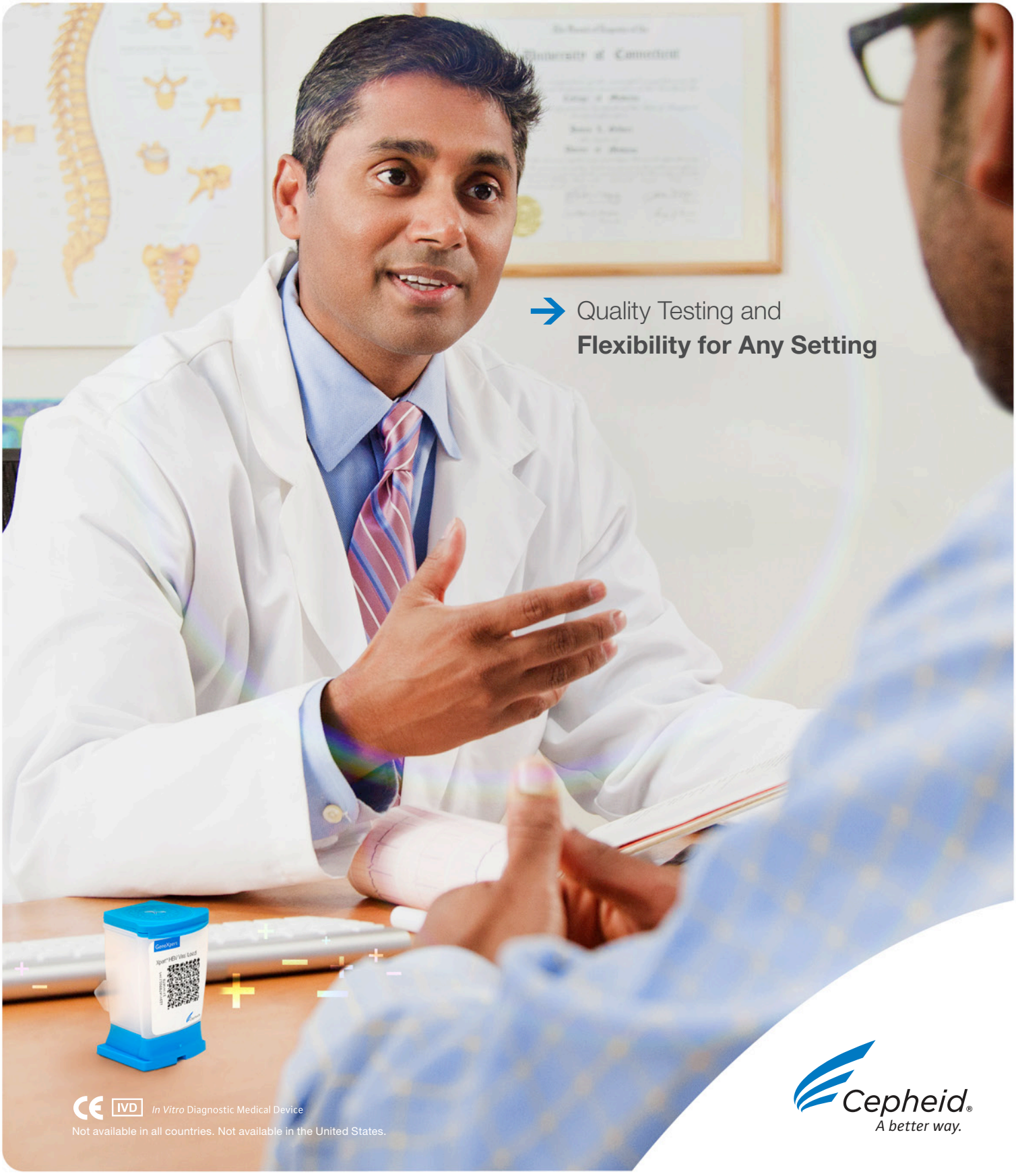
EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 708525**
Date: **2020-02-11**
Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

Date	Reference Number	Action
28 March 2019	9738780	First issue. Transfer from another Notified Body
17 June 2019	9786453	Addition of new product codes for the Xpert CT/NG device
09 August 2019	3057084	Change: extension to shelf life claim for the Xpert HBV Viral Load assay to 12 months; extension to shelf life claim for the Xpert HCV Viral Load assay to 18 months and an extension to shelf life claim for the Xpert HCV VL Fingerstick assay to 12 months.
20 September 2019	3069234	Addition of a new product for the Xpert HIV-1 Viral Load device.
Current	3145537	Renewal

Xpert® HBV Viral Load

Simplify Hepatitis B Treatment Management



CE IVD *In Vitro* Diagnostic Medical Device

Not available in all countries. Not available in the United States.

Cepheid®
A better way.

> In order to expand treatment of Hepatitis B, simplified and easy to use core service interventions are needed to implement effective HBV DNA Testing. Xpert® HBV Viral Load has the potential to simplify disease management by offering a flexible workflow for any testing setting and quality results in approximately an hour."

Professor Pietro Lampertico, MD, PhD
Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, Italy

The Goal

Elimination of Hepatitis by 2030

Viral hepatitis is one of the leading causes of death globally with 1.4 million deaths per year, as many as HIV/AIDS, tuberculosis or malaria. Hepatitis B and C viruses cause 95% of those deaths in the world.[1]

The WHO global health sector strategy to eliminate Viral Hepatitis as a major public health threat by 2030 requires considerable efforts from governments, healthcare authorities and communities.

Service delivery must be expanded to better manage the number of people living with Hepatitis B Virus (HBV).[1]

The Need

Efficient Treatment Delivery

- Although a vaccine for HBV exists, there is still no cure and lifelong treatment is needed for individuals already chronically infected with Hepatitis B Virus
- HBV rapid antibody testing is mainly done at point of care or in community based programmes but HBV viral load testing and monitoring is traditionally done in the laboratory with long turnaround times, which can result in more patients being lost to follow up and care
- Service coverage of core interventions are needed to expand prevention, testing and treatment for HBV

The Solution

Xpert HBV Viral Load on the GeneXpert® System

- Accurate and reliable quantification of HBV DNA in human serum or plasma
- Flexible thoughput for any testing setting with round the clock, on-demand results
- Simplify disease management with the possibility of having sample to viral load results less than one hour

The Impact

- **Improve Patient Care:** Same day results support better clinical decisions
- **Increase Efficiency:** High quality HBV viral load quantitative results for accurate treatment delivery
- **Strengthen Communities:** Quick decisions can help reduce drug resistance and lower transmission

Designed for both near patient testing and high throughput labs.

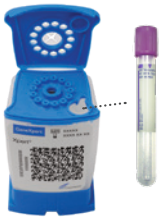
- **No Waiting:** Deliver rapid individual patient results in a single visit
- **Simple and organised:** True 24/7 random access accommodates other urgent test requests — i.e., Xpert® HCV Viral Load, Xpert® HIV-1 Viral Load, Xpert® MTB/RIF Ultra can run simultaneously on the same system
- **Improved Service:** Modular system can adapt to any throughput requirement from Health Clinics to National Reference Centers

Workflow:

2 Easy Steps

1

Transfer at least 1 mL of plasma or serum into the cartridge

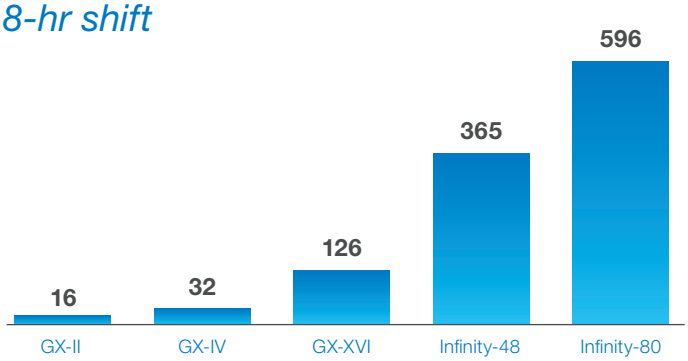


2

Scan, load cartridge and start test

System Throughput*

8-hr shift



* Operational throughput per 8-hr shift based on HBV Viral Load testing, internal analysis.

GeneXpert® Infinity-80

GeneXpert® I GeneXpert® II GeneXpert® IV GeneXpert® XVI

CATALOG INFORMATION

Xpert® HBV Viral Load	10 tests	GXHBV-VL-CE-10

Reference:

1 WHO. Global Health Sector Strategy on Viral Hepatitis 2016–2021. 2016 June. Accessed Aug 2020. https://apps.who.int/iris/bitstream/handle/10665/246177/WHO-HIV-2016.06-eng.pdf;jsessionid=E5D2C86E67F6CAC0258DDC6892B5A5E8?sequence=1

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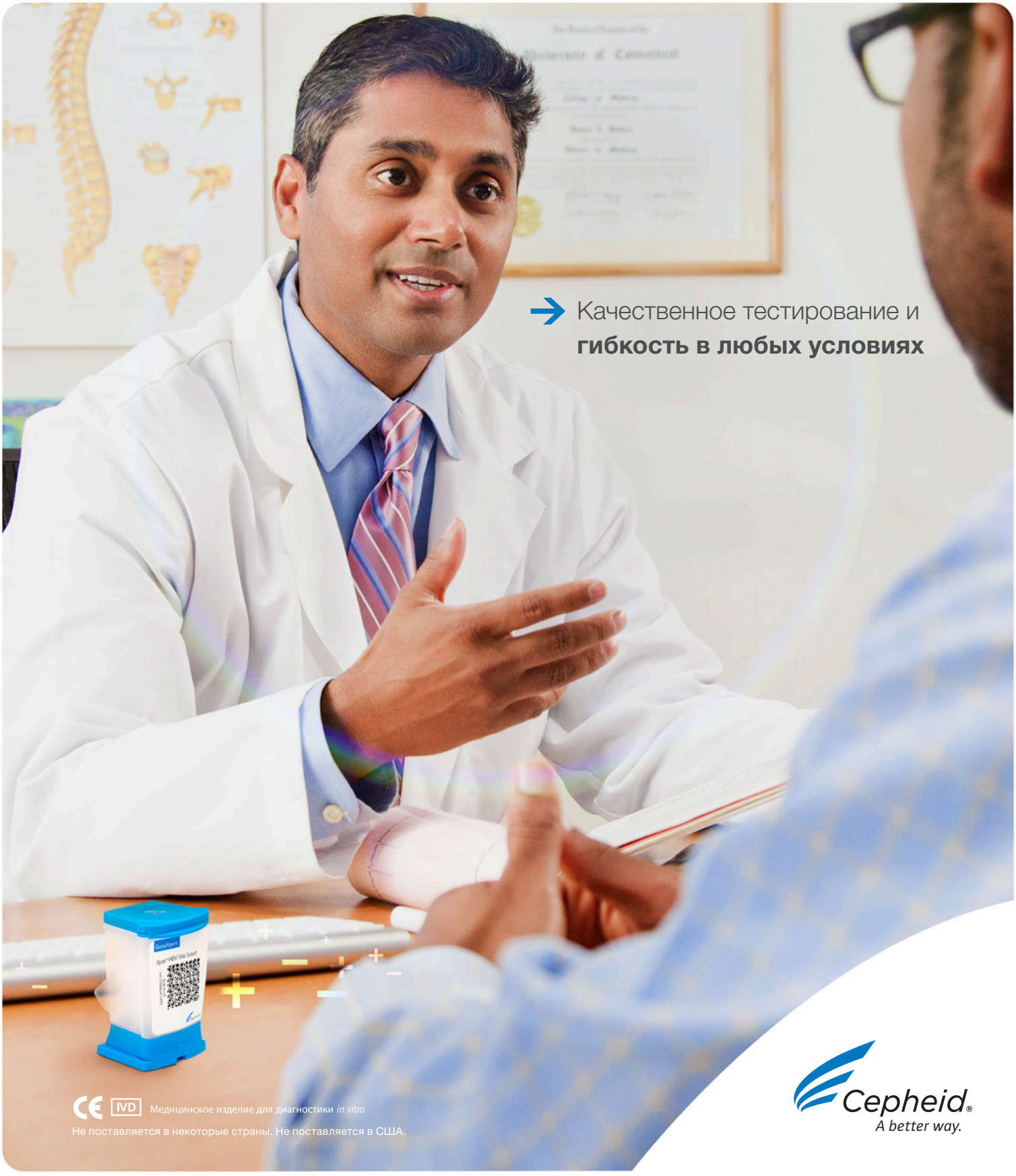
FAX **+33.563.82.53.01**
EMAIL **cepheid@cepheideurope.fr**

www.**Cepheidinternational**.com

Xpert® HBV Viral Load

Упростите проведение лечения гепатита B



CE IVD Медицинское изделие для диагностики *in vitro*

Не поставляется в некоторые страны. Не поставляется в США.

Cepheid®
A better way.

«Для расширения медицинской помощи лицам с гепатитом B необходимо проведение простых и доступных мероприятий с широким охватом по внедрению эффективного тестирования на ДНК HBV. Xpert® HBV Viral Load может упростить ведение заболевания, предлагая гибкость рабочего процесса в любых условиях тестирования и способность выдавать качественные результаты приблизительно за час.»

Профессор Пьетро Лампертико (Professor Pietro Lampertico), доктор медицины, доктор философии
Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Милан, Италия

Цель

Устранение гепатита к 2030 г

Вирусный гепатит является одной из ведущих причин смертности в мировом масштабе, приводя к 1,4 млн. смертей в год, что по порядку величины сравнимо со смертностью от ВИЧ/СПИД, туберкулеза или малярии. 95% этих случаев смерти обусловлены инфекциями, вызванными вирусами гепатита B и C.[1]

Стратегия ВОЗ в глобальном секторе здравоохранения по устранению вирусного гепатита как существенной угрозы здоровью населения к 2030 году требует от правительств, органов здравоохранения и общества приложения значительных усилий.

Необходимо расширить оказание помощи, увеличив охват инфицированных вирусом гепатита B (HBV).[1]

Потребность

Эффективное оказание медицинской помощи

- Хотя существует вакцина против HBV, средство для полного излечения до сих пор не найдено, и лица с хронической инфекцией, вызванной вирусом гепатита B, нуждаются в пожизненном лечении
- В лечебных учреждениях или в рамках программ обследования населения обычно проводится быстрое тестирование на антитела к HBV, однако тестирование и мониторинг вирусной нагрузки HBV традиционно происходит в лабораториях и отличается длительным временем выполнения, что может привести к потере контроля над многими пациентами и неоказанию им помощи
- Для повышения охвата профилактики, тестирования и лечения HBV необходимо проведение расширенных мероприятий

Решение

Тест Xpert HBV Viral Load на системе GeneXpert®

- Точное и надежное количественное определение ДНК HBV в сыворотке или плазме человека
- Гибкая производительность для любых условий тестирования с получением результатов по требованию в любое время суток
- Упрощение ведения заболевания с получением данных по вирусной нагрузке (от взятия образца до получения результата) менее чем за час

Влияние

- **Повышение качества лечения пациента:** получение результатов в тот же день ведет к принятию более адекватных клинических решений
- **Повышение эффективности:** Высококачественные количественные результаты по вирусной нагрузке HBV для проведения точного лечения
- **Улучшение эпидемиологической обстановки:** Быстрые решения помогают снизить резистентность к лекарствам и снизить вероятность передачи

Предназначен как для тестирования в месте обследования пациента, так и для высокопроизводительных лабораторий.

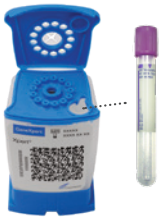
- **Отсутствие ожидания:** Быстрое получение результатов для отдельно взятого пациента за один визит
- **Простота и организация:** Истинный произвольный доступ в режиме 24/7 позволяет проводить обработку других срочных заказов на тестирование, т.е. на одной и той же системе могут одновременно проводиться тесты Xpert® HCV Viral Load, Xpert® HIV-1 Viral Load, Xpert® MTB/RIF Ultra
- **Улучшение обслуживания:** Модульную систему можно адаптировать под любые запросы, касающиеся производительности — от поликлиник до референсных лабораторий национального уровня

Рабочий процесс:

2 простых шага

1

Поместите в картридж не менее 1 мл плазмы или сыворотки

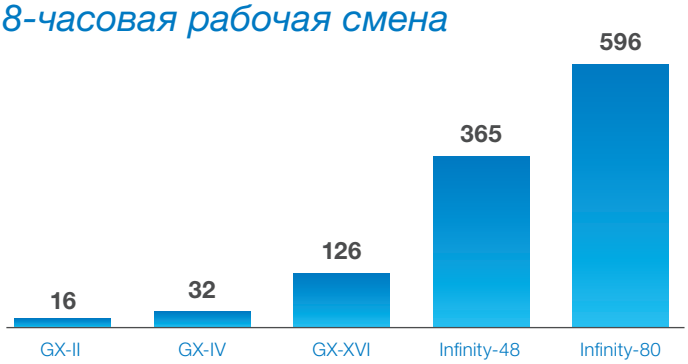


2

Отсканируйте данные, загрузите картридж и запустите тест

Производительность системы*

8-часовая рабочая смена



* Эксплуатационная производительность за 8-часовую рабочую смену при выполнении теста HBV Viral Load, внутренний анализ.

GeneXpert® I GeneXpert® II GeneXpert® IV GeneXpert® XVI GeneXpert® Infinity-80

		КАТАЛОЖНЫЙ НОМЕР
Xpert® HBV Viral Load	10 тестов	GXHBV-VL-CE-10

Справочная литература:

1 WHO. Global Health Sector Strategy on Viral Hepatitis 2016–2021. 2016 June. Accessed Aug 2020. https://apps.who.int/iris/bitstream/handle/10665/246177/WHO-HIV-2016.06-eng.pdf;jsessionid=E5D2C86E67F6CAC0258DDC6892B5A5E8?sequence=1

ШТАБ-КВАРТИРА КОРПОРАЦИИ

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ЭЛ. ПОЧТА **cepheid@cepheideurope.fr**

www.**Cepheidinternational**.com

Xpert® HCV VL Cartridge Preparation

- Xpert® HCV Viral Load

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit
www.cepheid.com or
www.cepheidinternational.com

Cepheid Technical Support

US office
(888) 838-3222, Option 2
techsupport@cepheid.com

European office
+33 563 825 319
support@cepheideurope.com

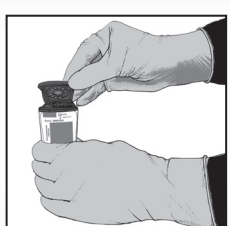
Prior to beginning this test:

1. Centrifuge the sample to separate the plasma/serum and red blood cells per the manufacturer's instruction.
2. Equilibrate the plasma/serum to room temperature (20-35 ºC).
3. Vortex for 15 seconds before use. If specimen is cloudy, clarify by a quick spin..

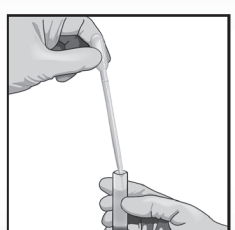
Cepheid®
A better way.

1 Take one Xpert cartridge for each sample.

2 Open the cartidge lid.



3 Aspirate the plasma/serum to just above the 1mL mark on the pipette.



4 Empty the contents into the sample chamber.

5 Close the cartridge lid.

6 Start the test within the timeframe specified in the package insert.

301-4917 Rev. A March 2015

Xpert® HBV VL Cartridge Preparation

- Xpert® HBV Viral Load

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit
www.cepheid.com or
www.cepheidinternational.com

Cepheid Technical Support

US office
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techsupport@cepheid.com

European office
+33 563 825 319
support@cepheideurope.com

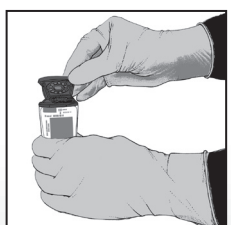
Prior to beginning this test:

1. Centrifuge the sample to separate the plasma/serum and red blood cells per the manufacturer's instruction.
2. Equilibrate the plasma/serum to room temperature (20-35 ºC).
3. Vortex for 10 seconds before use. If specimen is cloudy, clarify by a quick spin..

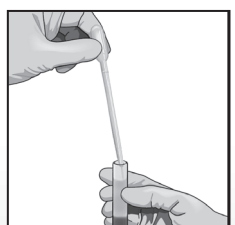
Cepheid®
A better way.

1 Take one Xpert cartridge for each sample.

2 Open the cartidge lid.



3 Aspirate the plasma/serum to just above the 1mL mark on the transfer pipette Or Aspirate just 0.6mL plasma/serum using precision pipette.



4 Empty the contents into the sample chamber.

5 Close the cartridge lid.

6 Start the test within 4 hours after adding the sample into the cartridge .

302-0140 Rev. A August 2018

Подготовка картриджа Xpert® HBV VL

- Xpert® HBV Viral Load

Подробные инструкции, меры предосторожности и предупреждения приводятся во вкладыше-инструкции.

Для получения копии паспорта безопасности посетите сайт www.cepheid.com или www.cepheidinternational.com

Служба технической поддержки компании Cepheid
Офис в США
(888) 838-3222, вариант 2
techsupport@cepheid.com

Представительство в Европе
+33 563 825 319
support@cepheideurope.com

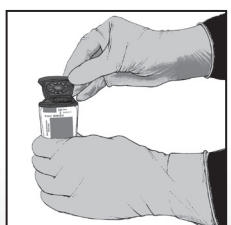
Перед выполнением данного теста:

1. Отделите плазму/сыворотку от эритроцитов путем центрифугирования образца, следуя инструкциям изготовителя.
2. Дождитесь прогрева плазмы/сыворотки до комнатной температуры (20-35 ºC).
3. Перед использованием выполните перемешивание на вихревой мешалке в течение 10 секунд. Мутный образец следует отцентрифугировать в течение непродолжительного времени.

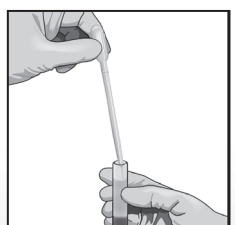
Cepheid®
A better way.

1 Возьмите по одному картриджу Xpert для каждого образца.

2 Откройте крышку картриджа.



3 Выполните аспирацию плазмы/сыворотки до уровня чуть выше метки 1 мкл пипеткой для переноса или 0,6 мл плазмы/сыворотки прецизионной пипеткой.



4 Внесите все содержимое пипетки в камеру для образца.

5 Закройте крышку картриджа.

6 Тест следует начать не позднее чем через 4 часа после внесения образца в картридж.

302-0140R, ред. A Август 2018 г.

GeneXpert®
Powered By CEPHEID INNOVATION

Xpert Check Package Insert

REF **XPERTCHECK-CE-5**

Cepheid®

In Vitro Diagnostic Medical Device IVD CE

301-3985, Rev. J October 2021

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Adobe® and Reader® are registered trademarks of Adobe Systems Incorporated.

Windows® is a registered trademark of Microsoft Corporation.

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Fax: +1.408.541.4192

Preface

About This Document

The *Xpert Check Package Insert* provides instructions on running Xpert Check software for checking module performance.

Safety Information

Read and understand any safety information presented in this document before you begin operating the instrument. Make sure you follow the precautionary statements presented in this guide:

Caution 	**Indicates that damage to the system, loss of data, or invalid results could occur if the user fails to comply with the advice given.**
Important	**Highlights information that is critical for the completion of a task or the optimal performance of the system.**
Note	Identifies information that applies only in special cases.

Related Documents

For other information outside the scope of this document, see the following publications:

- GeneXpert Dx Operator Manual
- GeneXpert Xpress User's Guide
- Infinity Operator Manual

Cepheid Headquarters Locations

Corporate Headquarters	European Headquarters
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089-1189 USA	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France
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Fax: +1 408.541.4192	Fax: +33.563.825 301
www.cepheid.com	www.cepheidinternational.com

Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

Contact Information

United States

Telephone: + 1 888.838.3222
Email: techsupport@cepheid.com

France

Telephone: + 33 563.825.319
Email: support@cepheideurope.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	*In vitro* diagnostic medical device
LOT	Batch code
	Do not reuse
	This type of symbol indicates a Warning or Caution for which there is no other identified symbol. Read the instructions following the symbol to avoid injury or equipment damage.
	Consult instructions for use
	Manufacturer
CC	Country of manufacture
Σ	Contains sufficient for <n> tests
	Expiration date
CONTROL	Control
CE	CE marking - European Conformity
EC REP	Authorized representative in the European Community
	Temperature limitation
	This type of warning label indicates a potential biological hazard risk. Biological samples such as tissues, body fluids, and blood of humans and/or animals have the potential to transmit infectious diseases. Follow your local, state/ provincial, and national safety regulations for handling and disposing the samples.

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EC REP

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CE IVD

Table of Contents

List of Figures

1 Introduction

Important **Read and understand this entire document before performing the data collection procedure.**

1.1 Proprietary Name

Xpert Check

1.2 Common or Usual Name

Xpert Check

1.3 Intended Use

The Xpert Check kit is part of a check, verification, and hardware test system for GeneXpert modules. The Xpert Check kit is used in GeneXpert DX, GeneXpert Xpress and Infinity systems, and cannot be used in the GeneXpert Omni system. The Xpert Check kit is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module.

1.4 Summary and Explanation

The GeneXpert (GX) module is the basis for all GeneXpert instrument systems worldwide. Cepheid recommends that the system be checked for proper operation on an annual basis. Based upon the usage and care of each system, checks may be recommended more frequently. The system is designed to detect module issues with the internal assay controls.

The Xpert Check kit includes reagents for the optical checking and performance verification of the module. Probe Check Controls (PCCs) verify reagent rehydration, PCR tube filling in the cartridge, probe integrity, and reagent stability. Thermal performance is verified via proprietary thermal probe chemistries, and module hardware performance is tested and verified by a suite of subsystem-specific tests which exercise all critical elements of the GX module.

The Xpert Check process consists of two phases. The first phase is the execution of module testing using the cartridges contained within this kit. The second phase consists of a Cepheid Quality Assurance Review, followed by the issuance of an Xpert Check code to complete the Xpert Check process. **The Xpert Check process is not complete until this code is applied to the system**.

1.5 Reagents and Instruments

1.5.1 Materials Provided

The Xpert Check kit contains the following:

Table 1-1. Kit Contents

Description	Quantity
Xpert Check cartridges with integrated reaction tubes	**5 per kit**
Each cartridge contains the following materials:	
• Bead 1	**1 per cartridge**
• Reagent 1	**1.0 mL per cartridge**
I-CORE Lens Cleaning Brush	**4 per kit**
PI/Software (P/N 950-0413)	**1 per kit**
Data CD	**1 per kit**

Note Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the **SUPPORT** tab.

1.5.2 Storage and Handling

- Store the Xpert Check cartridges at 2-28 °C. Wait at least 10 minutes after removal from cold storage before using, to allow a cartridge to reach ambient temperature.
- Use the cartridge within 48 hours of opening the foil pouch.
- Discard cartridges that have been removed from their foil-wrapped pouches outside of the approved usage interval.
- Do not use cartridges that have passed the expiration date.
- Do not open a cartridge lid until you are ready to perform testing.
- The cartridge lid must be opened (vented) prior to use of the cartridge; however, no sample is required for testing.
- Discard all used and unused materials, including cleaning brushes and cartridges once the Xpert Check session is completed.

Note Contents of cartridges are non-hazardous.

1.5.3 Materials Required but Not Provided

- GeneXpert Dx, GeneXpert Xpress or Infinity System with Cepheid-supplied computer and barcode scanner.
- GeneXpert instrument.

1.6 Limitations

- For use with GeneXpert modules (running GeneXpert Dx software version 4.4, or higher, GeneXpert Edge v1.0, GeneXpert Xpertise v6.3 or higher and GeneXpert Xpress software version 5.1 or higher). 4-color GeneXpert modules cannot run Xpert Check and must be tested by Cepheid Service. Xpert Check 1.5a is not compatible with systems running Windows XP.
- Use of the Xpert Check kit does not guarantee that the GeneXpert instrument will be free of hardware failures, nor does it take the place of a Cepheid Service Agreement.

1.7 Warnings and Precautions

Important

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Please contact: https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

- Even though Xpert Check cartridges do not contain hazardous chemicals, you should always follow your institution's safety procedures for working with chemicals.
- Do not add a sample or other reagents to the Xpert Check cartridges.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use cartridges from visibly damaged or compromised foil pouches.
- Contact your local Cepheid Technical Support office for replacement of damaged kit contents.
- Do not use a cartridge if it is dropped.
- Each single-use Xpert Check cartridge is used to process one test. Do not reuse spent cartridges.
- Each cleaning brush is intended for use in a single module. Do not re-use brushes in multiple modules.

- Do not open a cartridge package or break the lid seal until you are ready to perform testing.
- Allow the Xpert Check cartridge to come to ambient temperature prior to use if it has been placed in cold storage. Wait at least 10 minutes after removal from cold storage before using.
- Do not store single cartridges. Cartridges left over from an Xpert Check session, including pouched/unopened cartridges should be discarded along with spent cartridges.
- Do not use cartridges whose shelf life has expired. The system will detect expired cartridges and abort the test.
- Once a cartridge barcode has been scanned, do not substitute another cartridge in place of the scanned cartridge.
- If using an internet-enabled Xpert Check, it is recommended that up-to-date anti-virus software be installed on the desktop or laptop computer with updated virus definition files, prior to executing Xpert Check.
- Prior to running Xpert Check, ensure that the environmental operating temperature is within the correct limits (15 °C–30 °C). Xpert Check will render a system's modules unavailable if the internal temperature is above 40 °C. The internal temperature can be verified in the Maintenance section of the GeneXpert DX, Infinity or GeneXpert Xpress software. Do not proceed under these conditions.
- Xpert Check expects the same computer to be used throughout the entire process. The computer installed with the GeneXpert system should be used, and not another computer from a different GeneXpert system.
- The Xpert Check code will expire if not applied within 45 days of completion of running Xpert Check.

1.8 Chemical Hazards

According to the Globally Harmonized System for Classification and Labeling (GHS) Regulation, this material is not considered hazardous.

1.9 Assistance and Contact Information

For a complete listing of Cepheid technical support, service support, sales support, and headquarters contacts, please see Technical Assistance, in the Preface of this document.

1.10 Software Buttons, Icons and Symbols

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	**Information.** Touch or click this icon to obtain additional information. Displays the Information Key workspace screen which has an explanation of the various module icon displays.
	**Continue**. This icon is located at the bottom of most screens. Touch or Click this icon to advance the display to the next screen.
	**Continue to End.** Touching or clicking this icon moves the user to the last screen.
	**Exit**. Exits the Xpert Check application.
	**About**. Brings up the About screen which shows the name of the software, the software version number, copyright notice, etc.
	**Home**. Go to the Home screen.
	**Repeat/Retry**. Retry loading an Xpert check cartridge to attempt to check a module that has had an unsuccessful test of a minor nature or if the cartridge has not been vented by the user. Used on the 'Check Test' screen.
	**Back.** Touching or clicking this icon takes the user to the previous screen.
	**Cancel.** Cancel the current operation. In most cases this will mean going back to the previous screen. In some cases, it may mean going back to the screen before the one that started the current operation.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	**Select none of the modules for check.** Deselects all modules for checking. If you only want to check a few modules, you may deselect ALL of them, and then reselect only the ones you wish to check.
	**Select all of the modules for checking**. The default setting for the system.
	**Connectivity Status.** Indicates the system is able to reach the Xpert Connectivity Center.
	**Connectivity Status.** Indicates the system is not able to reach the Xpert Connectivity Center.
	**Module unsupported for Xpert Check.** Skip the current module and do NOT attempt to check the current module.
	Module selected for Xpert Check. Module will be included when Xpert Check is run.
	**Skip Current Module.** Skip the current module and do not attempt to Xpert Check the current module. Used on the 'Load Xpert Check Cartridges' screen.
	**Skip Remaining Modules.** Skip all the remaining modules and do NOT attempt to Xpert Check them. Used on the 'Load Xpert Check Cartridges' screen.

Table 1-2. Software Buttons, Icons and Symbols

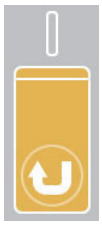
Symbol	Definition
	Module not selected for Xpert Check. Module will not be included when Xpert Check is run.
	**Module unavailable for Xpert Check.** Module will not be included when Xpert Check is run.
	Indicates a module with data collection in progress.
	Indicates data collection complete.
	**Retest required. I**ndicates an incomplete Xpert Check data collection. A message will notify the user that the test must be rerun. A further message will indicate if the existing cartridge can be reused for the test or if a new cartridge must be used.
	**Service required.** Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.

Table 1-2. Software Buttons, Icons and Symbols

Symbol	Definition
	**Lost communication.** Contact the Cepheid Authorized Service Provider (ASP) or your local Cepheid Technical Support office.
	**Burn.** Burn a CD containing the collected Xpert check information (for users without an active internet connection).
	**Collect Xpert Check Data.** Leads the user through the Xpert Check data collection process.
	**Enter Xpert Check code.** Go to the 'Enter Xpert Check Code' screen.
	**Xpert Check Status.** Go to the Xpert Check Status screen to review Xpert Check status.
	**Upload Xpert Check Data File.** Go to the 'Upload Xpert Check Code Data File' screen.
	**Upload Xpert Check Data CD.** Go to the 'Upload Xpert Check Code Data CD' screen.
	**Write Xpert Check Code.** Write an Xpert Check Code to a file.
	**Read Xpert Check Code.** Open a file to read the Xpert Check code.
	**Scan.** Turn the barcode scanner on, and accept the next scanned input.
	**View and Print.** Launch the Adobe Reader so you can view and then print a PDF file.

2 Procedure

2.1 System Preparation

Note Prepare the system for Xpert Check by following one of the four procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the Infinity-48, Infinity 48s or the Infinity-80.

Important **Authorized Service Providers (ASPs) who perform Xpert Check but won't be on-site when the Xpert Check code numbers come back (non-internet connection sites), should leave the user name and password for the users to log in later to enter the codes (see section 2.3.2).**

2.1.1 GeneXpert Dx Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Dx software.
4. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning.

2.1.2 GeneXpert Xpress Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert Xpress software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the GeneXpert Xpress software.
4. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning.

2.1.3 Infinity-48 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Restart the Xpertise software and switch the system from Automatic mode to Manual mode. Follow the instructions in the GeneXpert Infinity System Operator Manual for the Infinity-48.
4. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning.

2.1.4 Infinity-48s or Infinity-80 Preparation

1. Create an Administrator or Basic level User Name and Password in the GeneXpert software if one does not exist. Xpert Check requires this logon credential to be established prior to starting.
2. Have your Authorized Service Provider (ASP) code available before continuing to the next steps.
3. Exit the Infinity System software.
4. Open the glass doors following the instructions in the *Infinity Operator Manual*.
5. Go to Section 2.2, GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning.

2.2 GeneXpert Dx, GeneXpert Xpress and Infinity Optics Cleaning

This procedure describes the method for removing dust and tube debris from the surface of rod lenses of the excite and detect blocks for GeneXpert Dx, GeneXpert Xpress and Infinity modules prior to performing the Xpert Check procedure.

Materials Required or Recommended for Cleaning

- 300-8330 –Applicator brush (Quantity of four Included in the Xpert Check kit)
- Disposable gloves

Estimated Cleaning Time: 30 Seconds per module.

2.2.1 Lens Cleaning Procedure

1. Select the module to be checked and manually open the door of the module.
2. If necessary, remove the cartridge from the module.

Biological Risks

Remove the cartridge from the GeneXpert modules prior to cleaning. Failure to remove a cartridge could result in personnel being exposed to biological hazards and/or liquid biological materials spilling into the instrument and causing damage to the instrument.

3. Locate the brush provided in the Xpert Check kit (see Figure 2-1).

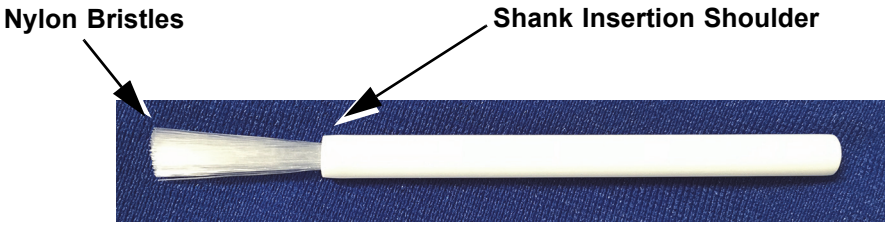


Figure 2-1. Lens Cleaning Brush (300-8330)

Note

The brush is designed so that it will easily insert into the I-CORE slit and make contact with the rod lenses of the excite and detect blocks.

Biological Risks

Make sure you wear disposable gloves for the cleaning process. Wearing gloves prevents you from being exposed to biologically hazardous materials.

4. Wearing disposable gloves, insert the brush into the I-CORE slit in a tilted manner up to the shank insertion shoulder, as shown in Figure 2-2.

Note

Make sure that all the bristles are fully inserted (up to the shoulder of the plastic shank of the brush) so that it does not cause unnecessary damage to the brush.

Caution

Do not insert any objects into the I-CORE slit except the provided brush. Inserting any other object may damage the I-CORE.

Caution

Do not apply any solution (such as ethanol or bleach) onto the brush bristles. The brush must be completely dry when inserting it into the I-CORE slit.

Important

The brush is intended for single-use and should not be used on more than one module. Use a new brush for each module to be cleaned.

Figure 2-2. Inserting the Cleaning Brush into the I-CORE Slit

5. Insert the brush into the I-CORE slit completely up to the plastic shank (shoulder) of the brush. Hold the brush firmly in the I-CORE slit, and perform cleaning of the rod lenses as described below. The entire cleaning process should take approximately 30 seconds per module.

Note

Cleaning is done by moving the brush in an up and down direction within the I-CORE slit. Brush rotation, even if it has to be done, is not the main action that results in optics cleaning.

   A. Begin by brushing from the top of the I-CORE slit to the bottom, making sure to apply a uniform pressure when brushing from the top to the bottom of the I-CORE slit. This will ensure that most of the tube debris and dust is brushed off from the surface of the lenses.

   B. Rotate the brush from left to right and back again, approximately 180°.

   C. Brush once more from the top of the I-CORE slit to the bottom.

   D. Rotate the brush again from left to right and back again, approximately 180°.

   E. Finally, brush again from the top of the I-CORE slit to the bottom.

6. When lens cleaning is complete, remove and discard the used brush and gloves as hazardous waste.

Important

Dispose of gloves and brushes according to your institution's safety policies and procedures for hazardous waste.

7. Proceed to Section 2.3, Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and Infinity.

2.3 Data Collection Procedure: GeneXpert Dx, GeneXpert Xpress and Infinity

Important

Before collecting data, be sure to prepare the system for checking as described in Section 2.1, System Preparation.
Internet-connected users should verify their system's connectivity status prior to beginning the Xpert Check process.

Note

Throughout this procedure, when making an onscreen button or icon selection, use the touchscreen on the GeneXpert Xpress system by touching the button or icon with your finger. When using the GeneXpert Dx or Infinity system, use a mouse to select, by clicking the desired button or icon.

Note

Use care in inserting CD1 into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Place Software CD1 in the computer connected to the GeneXpert Dx. For the GeneXpert Dx system using an external DVD drive and for the GeneXpert Xpress and Infinity systems, connect the DVD drive following the instructions in the GeneXpert Dx Operator Manual, the GeneXpert Xpress User's Guide or the Infinity Operator Manual, and insert the CD into the DVD drive.
2. For a GeneXpert Xpress system, follow the procedure in Step A., for GeneXpert Dx and Infinity, follow the procedure in Step B.:
   A. **GeneXpert Xpress** On the computer desktop, touch and hold the **Computer** icon and a drop-down menu will appear. Touch **Open**, then touch and hold the applicable drive letter for your DVD drive.
   Touch **Open** from the drop-down menu, and the files located on the CD will then be displayed.
   Find, touch and hold the **XpertCheck.exe** application, and when the drop-down menu appears, touch **Run** to install as administrator. When the software has been installed, a "wrench" icon will appear on the desktop.
   B. **GeneXpert Dx and Infinity:** On the computer desktop, right-click the **Computer** icon and a drop-down menu will appear. Click **Open**, then right-click on the applicable drive letter for your DVD drive.
   Select **Open** from the drop-down menu, and the files located on the CD will then be displayed.
   Find and right-click the **XpertCheck.exe** application, and when the drop-down menu appears, click **Run** to install as Administrator. When the software has been installed, a "wrench" icon will appear on the desktop.

Note

The software may take some time to load from the CD.

Note

The software may take some time to load from the CD.

3. Depending on your system, either touch or double-click the "wrench" icon to launch the Xpert Check program.

4. The License Agreement screen appears first. Use the scroll bar to read through the entire document. You will be asked to select (touch or click) the check box (bottom of the screen) to verify that you have read and agree to the License Agreement before continuing. See Figure 2-3.

Note

The Xpert Check software runs on Windows 7 or Windows 10. The screens shown in this manual are from Xpert Check software running on Windows 7. Screens for Xpert Check software running on Windows 10 will be similar.

Important

After January 14, 2020, Microsoft will no longer provide security updates or support for PCs running Windows 7. It is recommended that you upgrade to Windows 10.

Please contact: https://www.microsoft.com/en-us/microsoft-365/windows/end-of-windows-7-support for Windows 7 support information.

In addition, please contact your local Cepheid Technical Support if you have questions about using Windows 7.

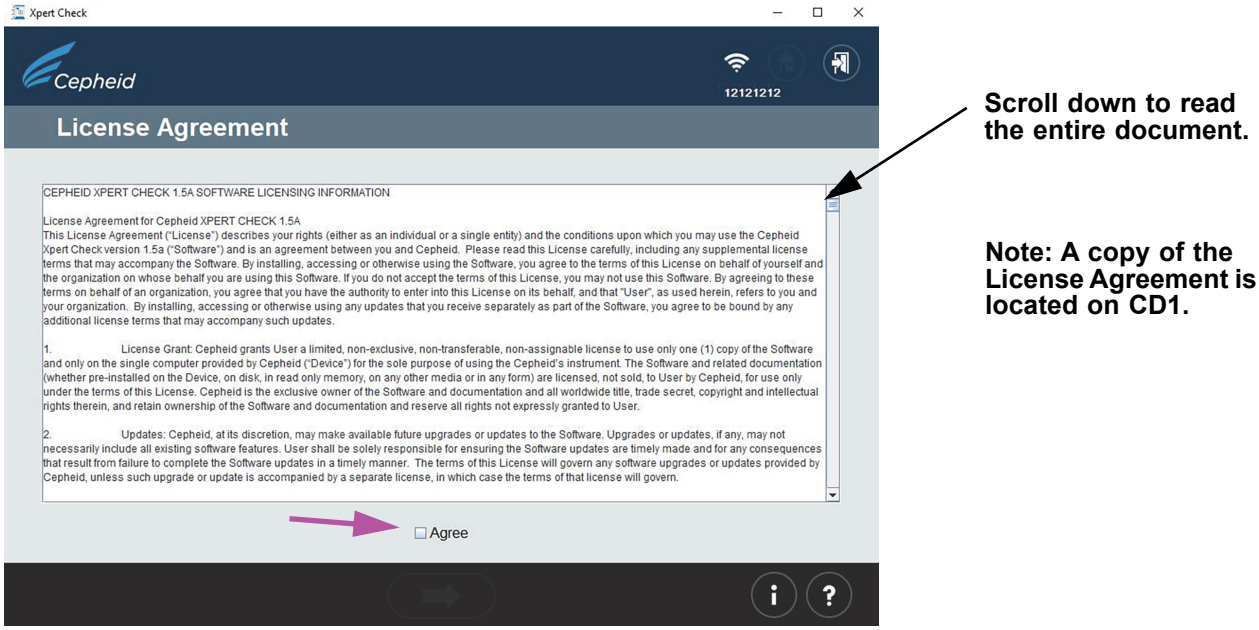


Figure 2-3. License Agreement Screen

5. After agreeing to the License Agreement, the Login screen will appear. Log in with your GeneXpert Dx, GeneXpert Xpress or Infinity designated Administrator level **USER NAME** and **PASSWORD** (previously assigned to you by your system administrator). After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen. See Figure 2-4.

Note

On the GeneXpert Xpress system, touching any field for inputting usernames, passwords, text, etc., will cause a virtual keyboard to appear for data entry. To close the keyboard, touch the **X** key in the upper right corner of the keyboard.

Note

The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software.

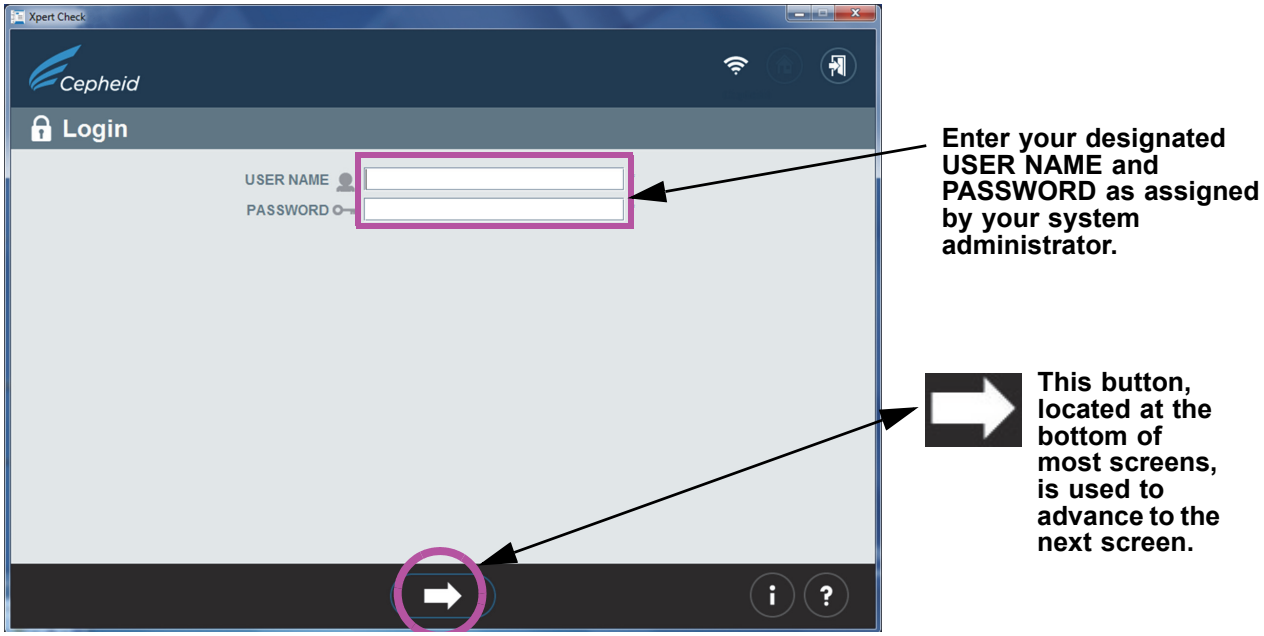


Figure 2-4. Xpert Check Login Screen

In case of a login error, the following screen will appear. See Figure 2-5.

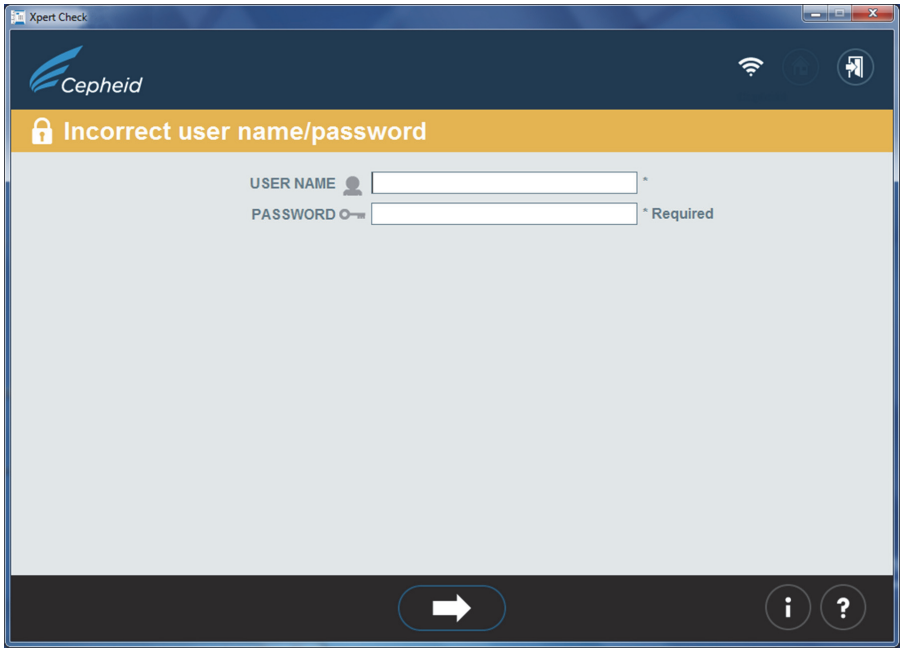


Figure 2-5. Login Error Screen

6. If a login error occurs, examine the **USER NAME** and **PASSWORD** entries for errors. If necessary, reenter the information and retry. After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the Xpert Check Home screen.

7. Obtain a sufficient number of cartridges for the number of modules to be tested.

Important **Do not open cartridge packages until you are ready to scan the cartridge barcode (in Step 17).**

Note When determining the number of cartridges that will be needed for this test, the user should be aware of the number of modules that they will be checking.

8. Touch or click the **Collect Xpert Check Data** icon on the Home screen (See Figure 2-6). After a few seconds, the first Contact Information screen (Figure 2-7) will appear.

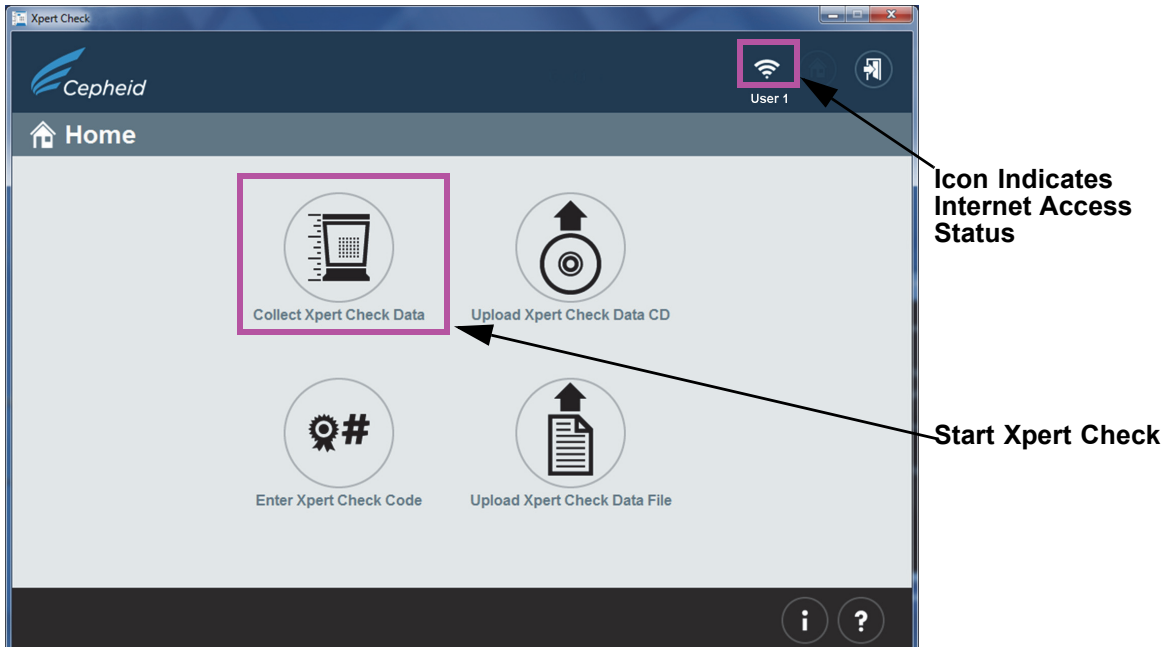


Figure 2-6. Home Screen

9. When the first of two Contact Information screens appear (see Figure 2-7 and Figure 2-8), fill out the fields in the two screens. Use the large navigation arrows at the bottom of the screens to move between the two screens.

Note GeneXpert Xpress: When you touch a field, an onscreen keyboard appears for entering data.

Note that fields marked with "*" (at the right of the entry area) are mandatory fields.

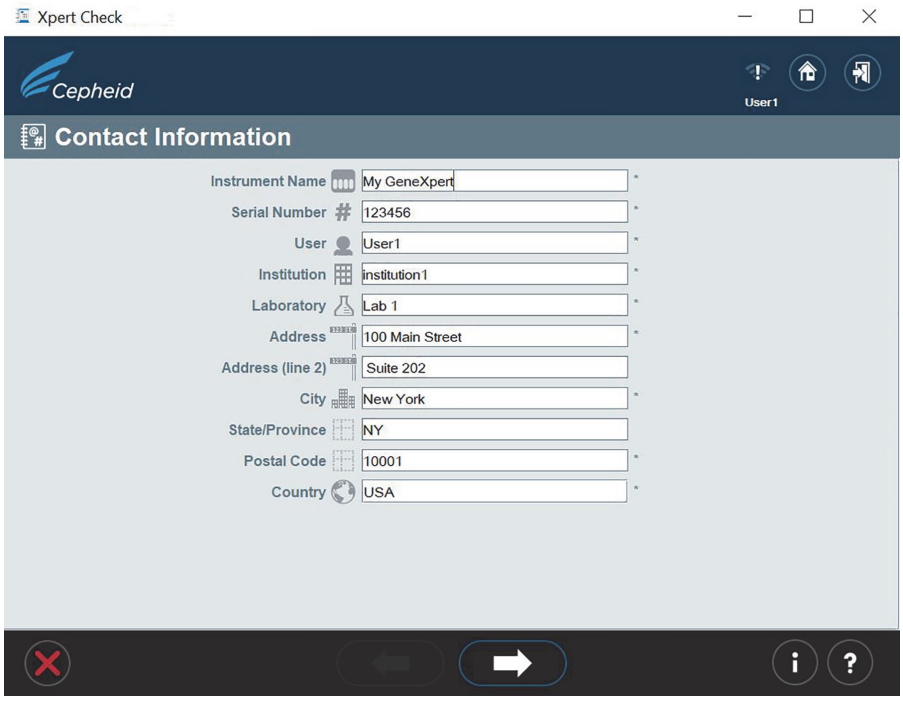
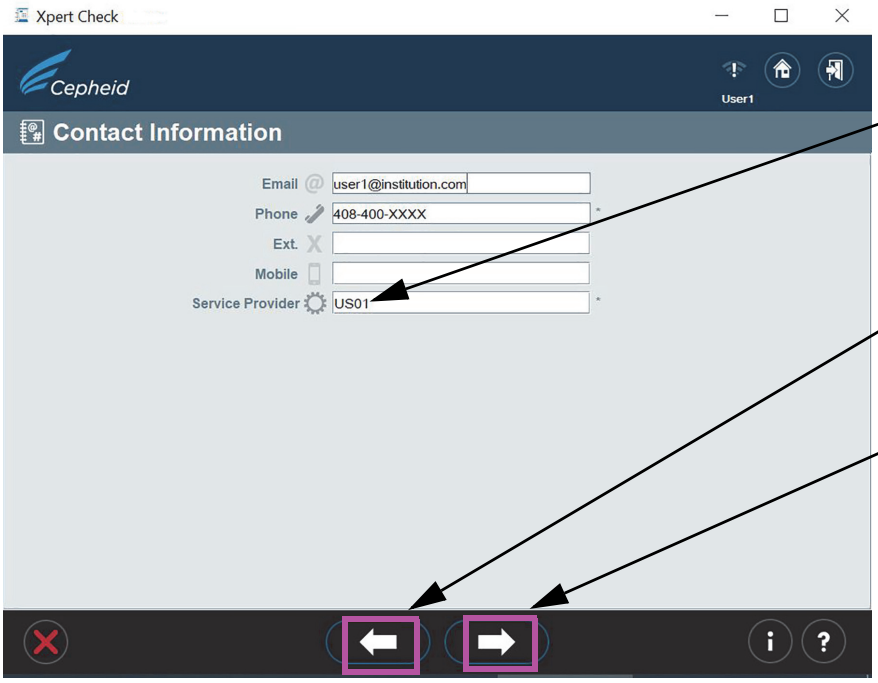


Figure 2-7. Contact Information Screen - Page 1



In this mandatory field, enter your Authorized Service Provider's ID code. The ID code is four characters, as described in the note below.

Clicking on this icon will take the user back to the first Contact Information screen

Clicking on this icon will take the user to the Open Module Doors screen

Figure 2-8. Contact Information Screen - Page 2

Note

The ASP-provided ID code for the Service Provider on the Contact Information screen consists of four characters. (As examples: US01, 1203, etc.)

10. When all information has been entered, touch or click the forward arrow button at the bottom of page 2 of the Contact Information screen. The Open Module Doors

screen will appear. See Figure 2-9. Manually open all module doors to enable cartridge loading.

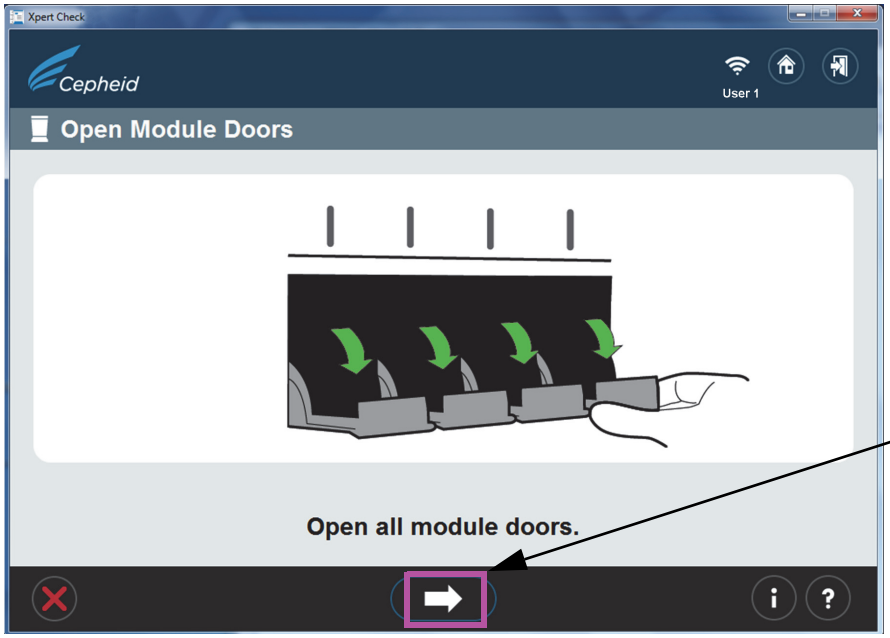


Figure 2-9. Open Module Doors Screen

11. After opening all the module doors, touch or click the forward arrow button at the bottom of the screen. The Module preparation screen may appear, showing the message **Wait while modules are being prepared.** (See Figure 2-10.)

Important

Note that the Module preparation screen will appear only if the firmware in the modules is not 3.0.3. The screen indicates that the software is upgrading/downgrading the firmware to the modules. The next screen you see will be the screen shown in Figure 2-11, the Select Modules screen.

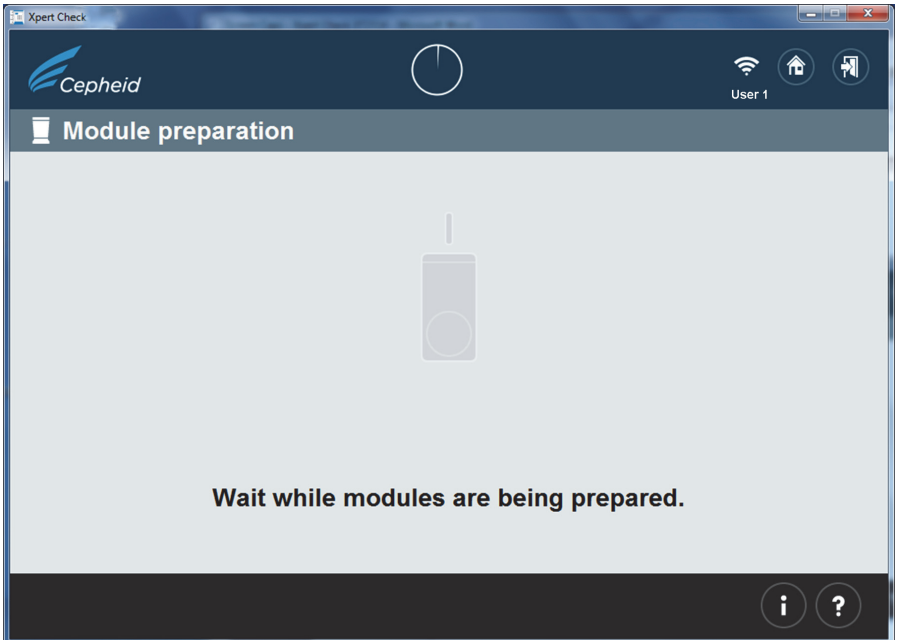


Figure 2-10. Module preparation Screen

12. Follow the on-screen software instructions in Figure 2-11. By default, all detected modules will be marked as selected for checking.

    On this screen, the user can touch or click individual module icons to exclude the modules from being checked, if required. The module icons will disappear as they are excluded.

Note

For excluded modules (not selected for checking), the door position (open or closed) does not matter.

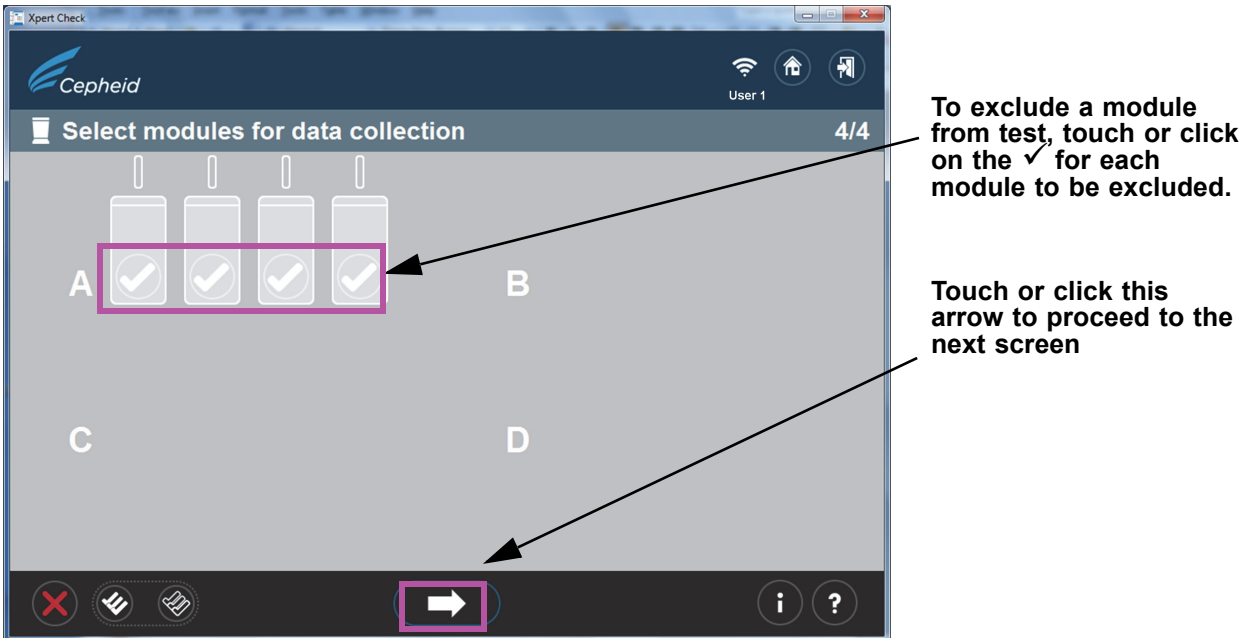


Figure 2-11. Select modules for data collection Screen

Important

GeneXpert-XVI and Infinity systems only: When selecting modules on screen, make a note of which module lights are blinking on the system as you select each bank, to ensure cartridges are placed in the correct modules for testing.

13. After confirming the module selection shown in Figure 2-11, touch or click the white arrow at the bottom of the screen overlay, to begin scanning cartridges. If the module selection shown is incorrect, touch or click the red **X** at the bottom left corner of the screen to return to the Select Modules screen and change your selection. See Figure 2-12.

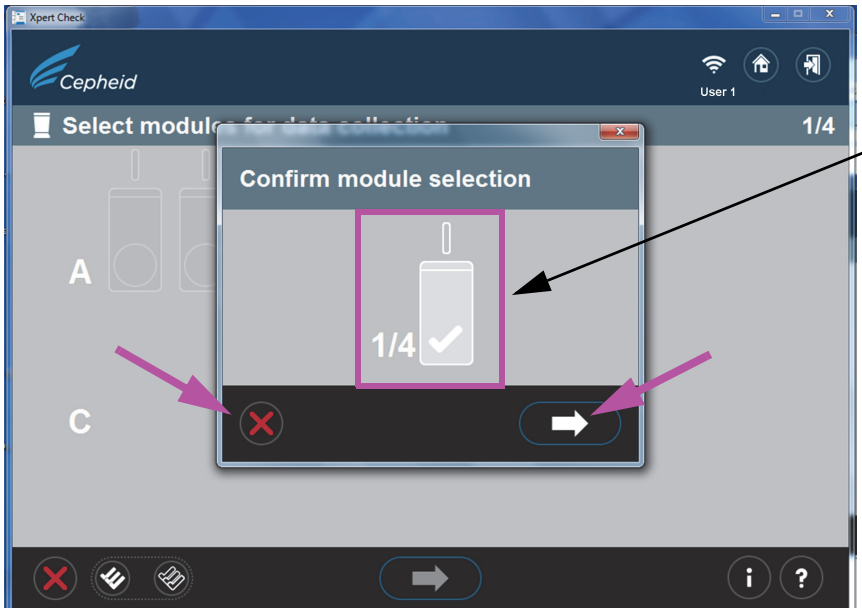


Figure 2-12. Confirm module selection Screen

14. In case of an error in the preceding step, in which either no modules have been selected, or all modules have been excluded, one of the following screens will appear (Figure 2-13). Follow the on-screen instructions to select a module, or start over by returning to the Home screen or exiting the program.

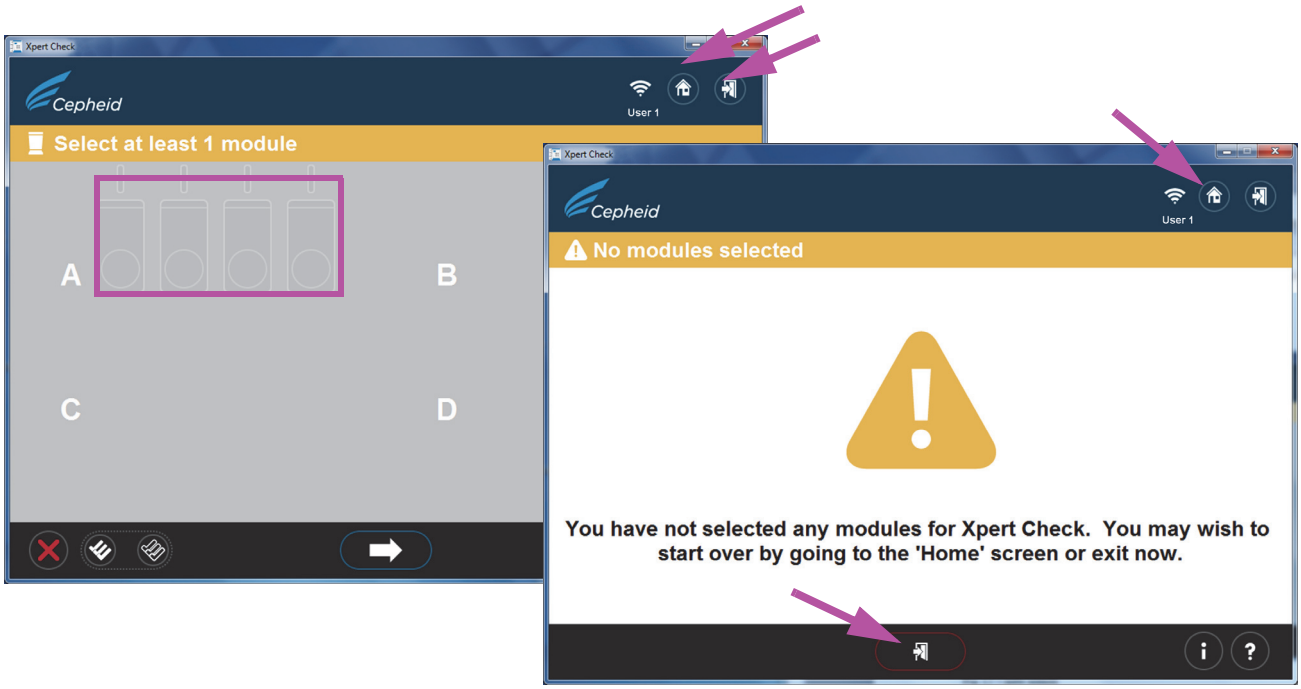


Figure 2-13. Error Screen Examples

15. After confirming your module selection, you will advance to the Scan cartridge screen, where you will be prompted to scan the barcode on the Xpert Check cartridge.

Note Verify you have enough cartridges on hand to perform the check procedure for the desired number of modules.

16. Remove the test kit cartridge from the package for the module you've previously selected, opening only one cartridge at a time.

Important **Allow the cartridge to reach ambient temperature before proceeding. Do not remove a cartridge from refrigerated storage and immediately use the cartridge to run this test.**

17. Scan the cartridge barcode. Figure 2-14 shows a cartridge barcode being scanned. Do not substitute a cartridge with another after it's been scanned.

Note If the barcode cannot be scanned, skip the cartridge and contact your ASP or local Cepheid Technical Support office for a replacement cartridge, if necessary. If the barcode scanner is damaged, missing or incorrectly configured, contact your ASP or local Cepheid Technical Support office for guidance.

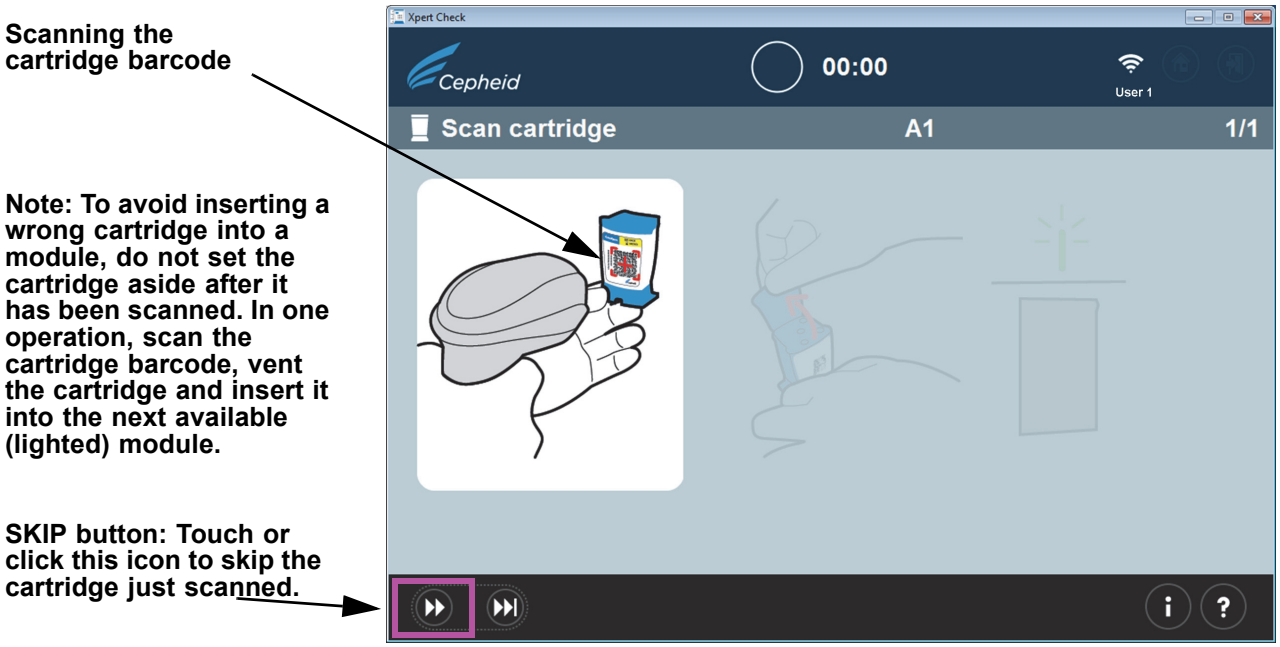


Figure 2-14. Scanning the Cartridge Barcode Screen

A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in Step B through Step E below.

Important **Do Not add a sample or reagent to the cartridge. Use ONLY the cartridges in the Xpert Check kit provided.**

Note After a cartridge barcode is scanned a green light will blink on the system above the module door where the cartridge is to be loaded. (See Figure 2-17.)

Note

If, for some reason, you want to skip the cartridge just scanned, touch or click the **SKIP** button at the bottom of the screen. An overlay, shown in Figure 2-15, will appear, asking for confirmation on skipping the cartridge. To SKIP the cartridge, touch or click the forward arrow at the bottom of the confirmation screen. To proceed without skipping the cartridge, touch or click the **X** icon at the left bottom corner of the screen. You are urged to rescan a cartridge (or substitute a new cartridge if necessary) to ensure a module is not skipped.

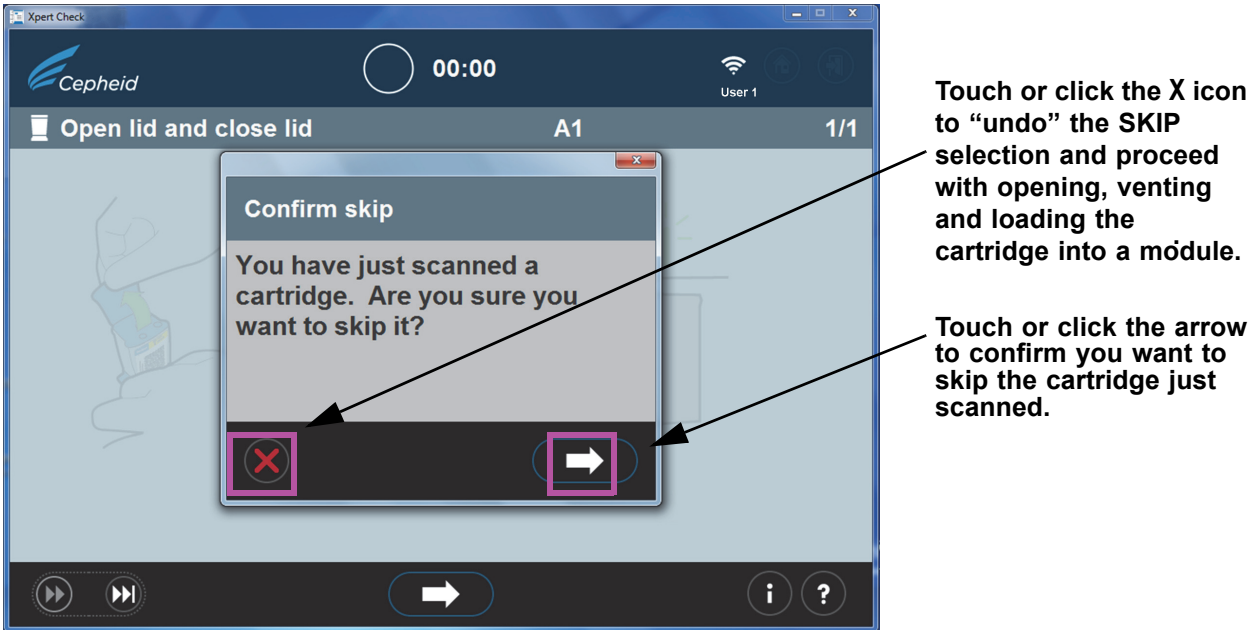


Figure 2-15. Confirm skip Screen

B. Venting the cartridge (shown in Figure 2-16), for two seconds is sufficient. This screen is animated, showing the cartridge lid being opened and closed. After venting, touch or click the forward arrow at the bottom of the screen to continue.

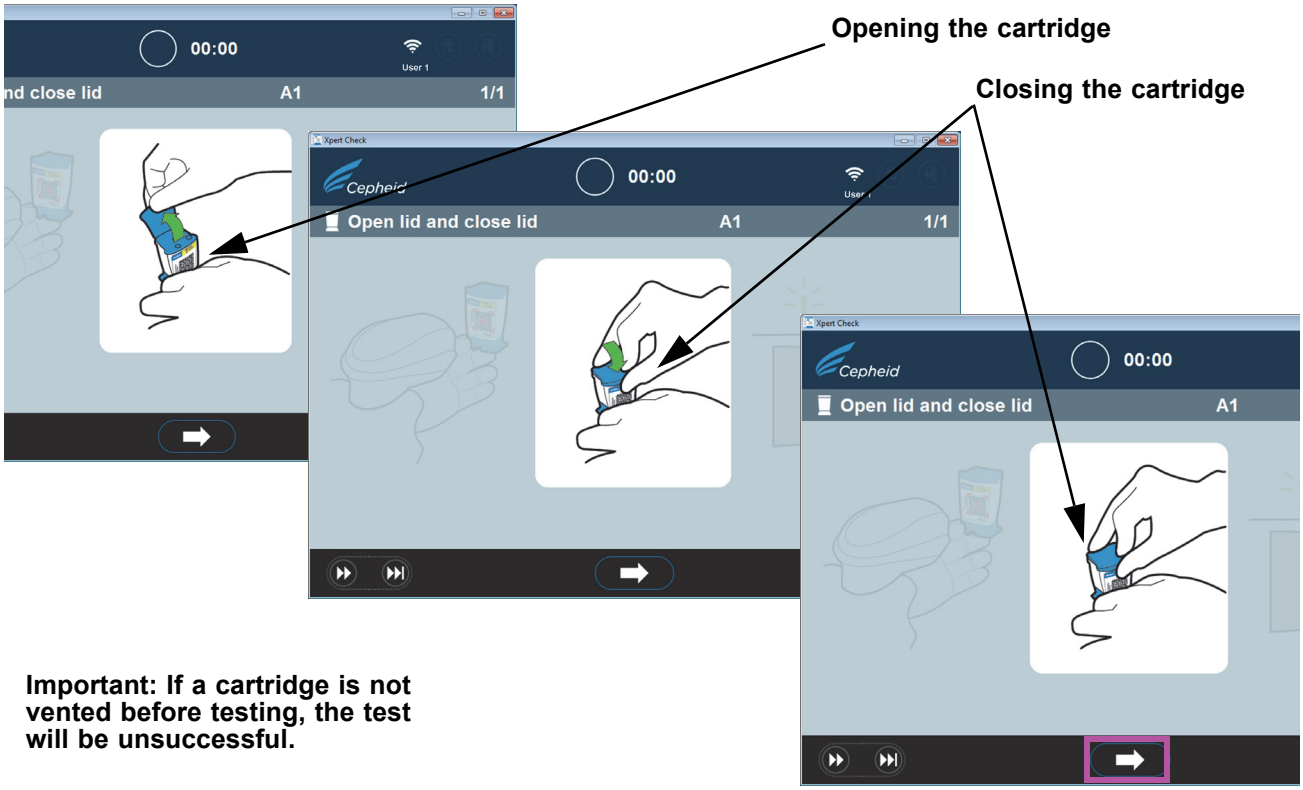


Figure 2-16. Venting the Cartridge by Opening and Closing the Cartridge Lid - Animated Screen

C. Close the cartridge lid and ensure the module door is fully opened to receive the cartridge.

D. Load the cartridge into the module (with the cartridge reaction tube (tab) facing away from you), as directed by the animated software screens. See Figure 2-17.

Note

Be sure to load scanned cartridges in sequence in the next available module. This will avoid loading cartridges in the wrong location or leaving modules empty.

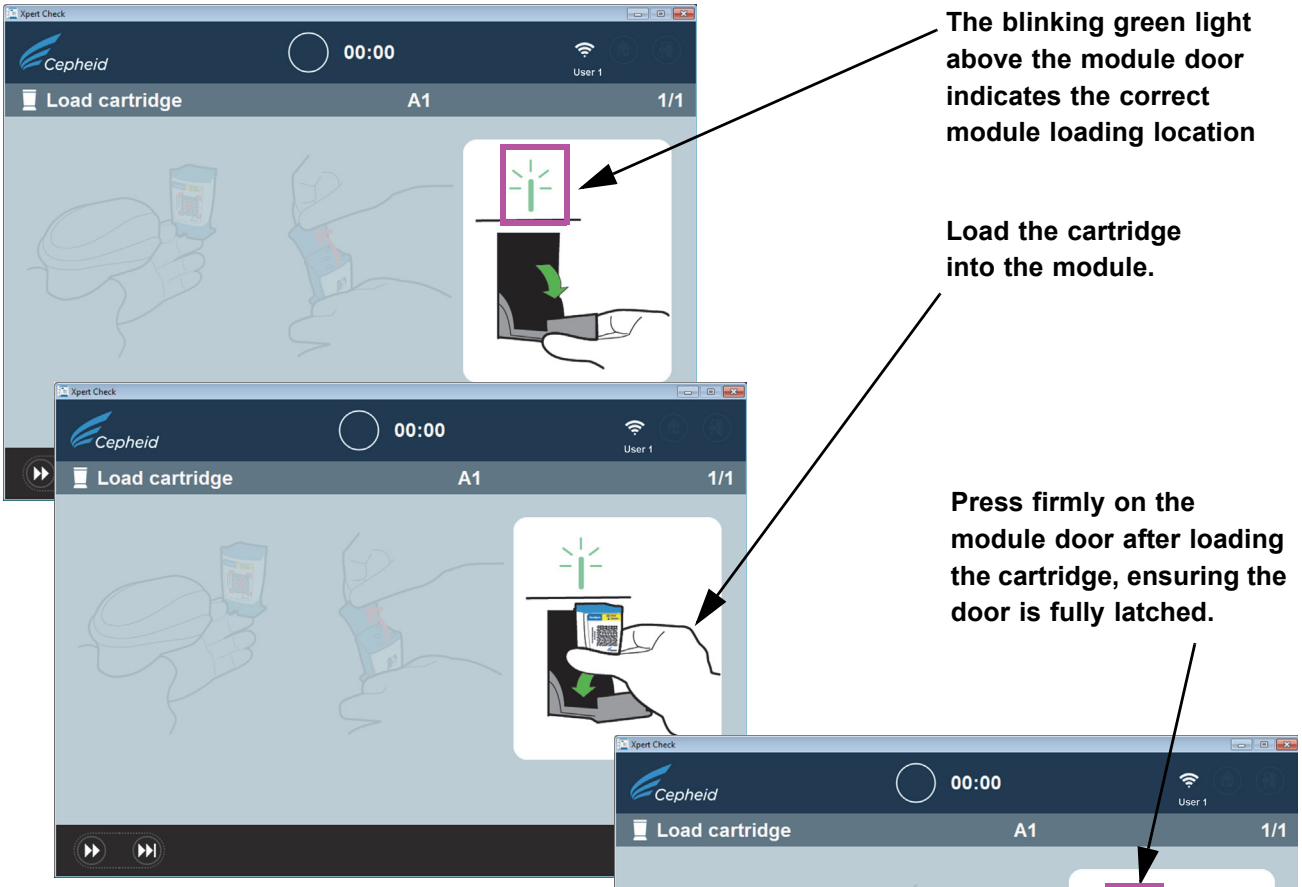


Figure 2-17. Loading the Cartridge into the Module

E. If you are checking additional modules, continue by scanning the next cartridge. Place each individually scanned cartridge into the next selected open module, pressing the module door securely closed until it latches. **As each module door is closed and latched, data collection will automatically start on that specific module.** The blinking green light above the module will then become steady green, indicating that checking has started.

Important

If a module door is not closed completely (until it latches) after loading a cartridge, the screen will continue to display a message to insert a cartridge, and the check will not run.

If you are unable to close and latch a module door after several tries, touch or click the SKIP button at the bottom of the screen to skip the module with the faulty door and move ahead. Notify your ASP or local Cepheid Technical Support office so the module can be serviced.

18. Checking will take approximately 20 minutes to complete after the final module has been loaded for testing. When checking begins, the Data collection in progress screen appears, as shown in Figure 2-18.

Important

If necessary, a retest of a previously run module may be started without waiting for the present module to complete its test, as described in steps 19b through 19d.

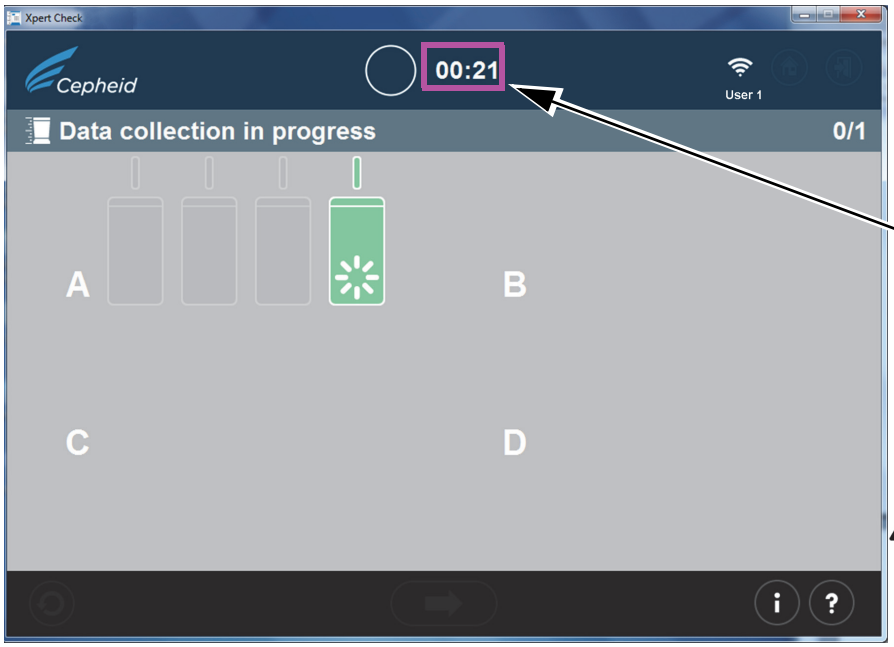


Figure 2-18. Data Collection Screen

Important

If you do not have an internet connection, skip to section 2.2.1 for the remainder of this procedure. If you have an internet connection, continue with step 19.

19. After test completion, the module door will open and the light above the module door will turn off. Screens similar to those shown in Figure 2-19 or Figure 2-20 will appear. Touch or click the right arrow to continue.

    A. Figure 2-19 shows the completion of a successful Xpert Check data collection.

    When the test is complete, touch or click the forward button at the bottom of the screen to begin uploading Xpert Check test results to the Xpert Connectivity Center.

Important

When uploading test results, especially multiple files, verify the selected folder destination is correct.

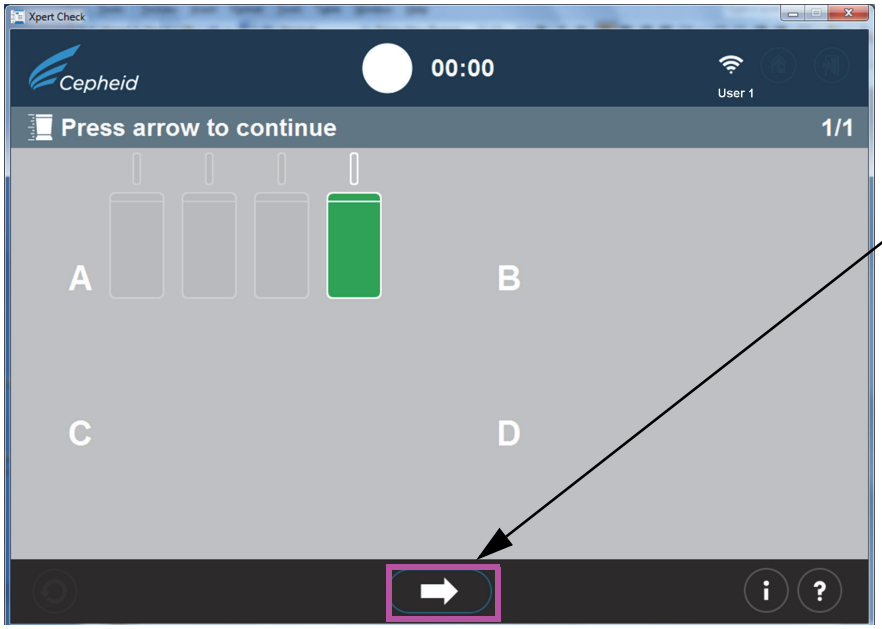


Figure 2-19. Test Completion Screen - Successful

B. If the test was unsuccessful, the screen shown in Figure 2-20 will appear, showing module status. A test retry must be performed. Touch or click the **Retry** icon in the lower left-hand corner of the screen.

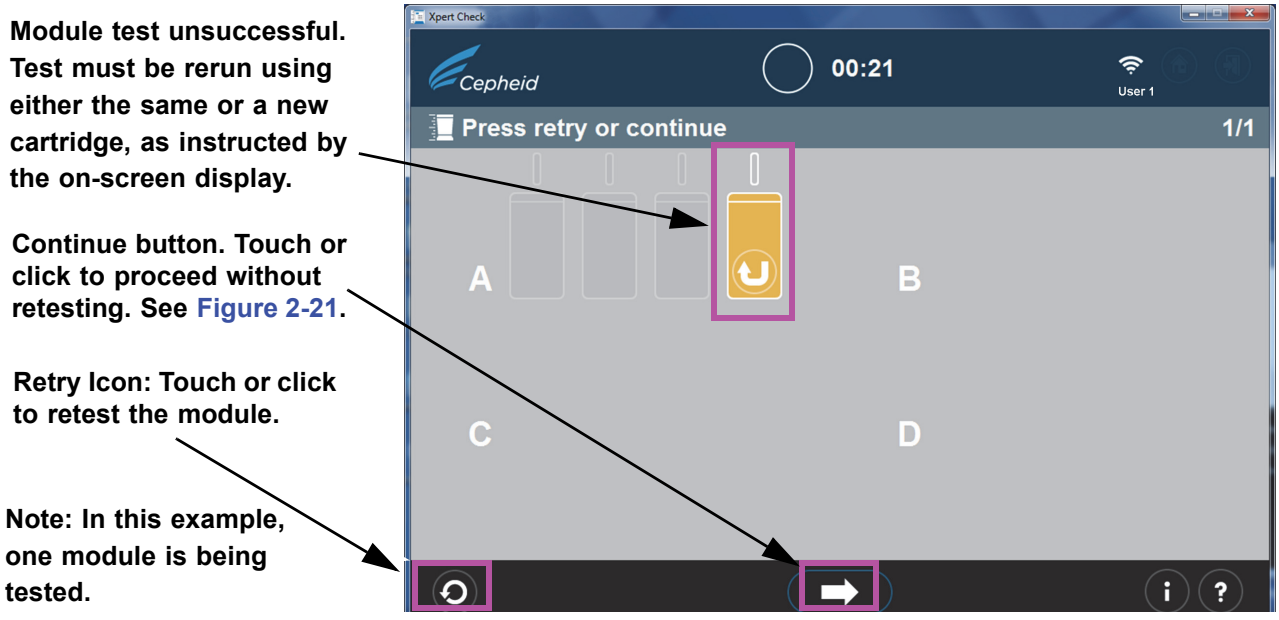


Figure 2-20. Test Completion Screen - Unsuccessful Module Checking Example

C. If the **Continue** arrow at the bottom of the screen is pressed when there is an unsuccessful module test displayed (as shown in Figure 2-20), the Confirm continue screen will appear. See Figure 2-21.

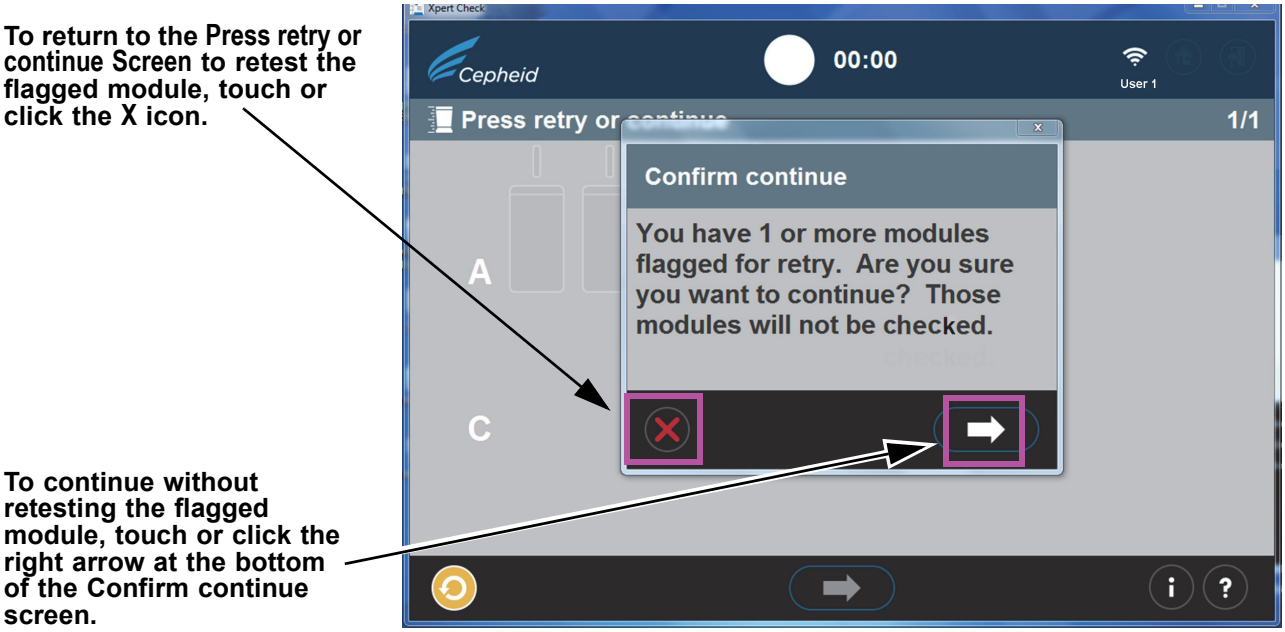


Figure 2-21. Confirm Continue Screen Overlay

You have the option of continuing by touching or clicking the right arrow on the Confirm continue screen overlay. Choosing this option will result in the flagged module not being retested, and you will begin uploading check data as described in Step 20.

Another option is to return to the Press retry or continue screen to Retry (retest) the flagged module by clicking the red **X** icon at the bottom left of the Confirm continue screen. The Retry procedure is described in Step D which follows.

D. If the Retry icon (shown above in Figure 2-21 at the bottom of the screen) appears, touch or click the Retry icon and you will return to the Scan Barcode screen (Figure 2-14) to complete the retest on the affected module(s).

Note that the retest can be of two possible types:

1) Retry with the same cartridge: For example, a message may appear telling you to vent the cartridge, rescan it, and put it back in the module.

2) Retry with a new cartridge: If the cartridge was defective, or had already been used, you will be asked to replace it by scanning the barcode on a new cartridge, venting it, and loading it into the module.

Note

During the course of running retests, modules may need to be skipped if the user runs out of Xpert Check cartridges. Please contact your ASP or local Cepheid Technical Support office for additional Xpert Check cartridges. Rerun Xpert Check on any modules that were skipped.

Note

At the completion of the Xpert Check data collection process, modules determined to require service will be flagged with an orange module icon (See Figure 2-20). Please contact your local ASP or local Cepheid Technical Support office for further assistance in servicing or replacing modules.

20. After successful test completion and Xpert Check data collection, touch or click the forward arrow to display the screen shown in Figure 2-22, if you have an active

internet connection. However, if you have never been internet connected, or have lost your functioning internet connection sometime during the Xpert Check test, a Download Xpert Check code error screen or an Upload incomplete error screen (Figure 2-23) may appear instead, instructing you to write Xpert Check data to a data CD to send to your ASP or local Cepheid Technical Support office. In this case, continue to the instructions beginning at Step 4 (under Section 2.3.1) of this procedure to continue as a user without an internet connection.

Note

With a functioning internet connection, the system should proceed normally (with Step 21), and the Xpert Check code should begin downloading, as shown in Figure 2-24.

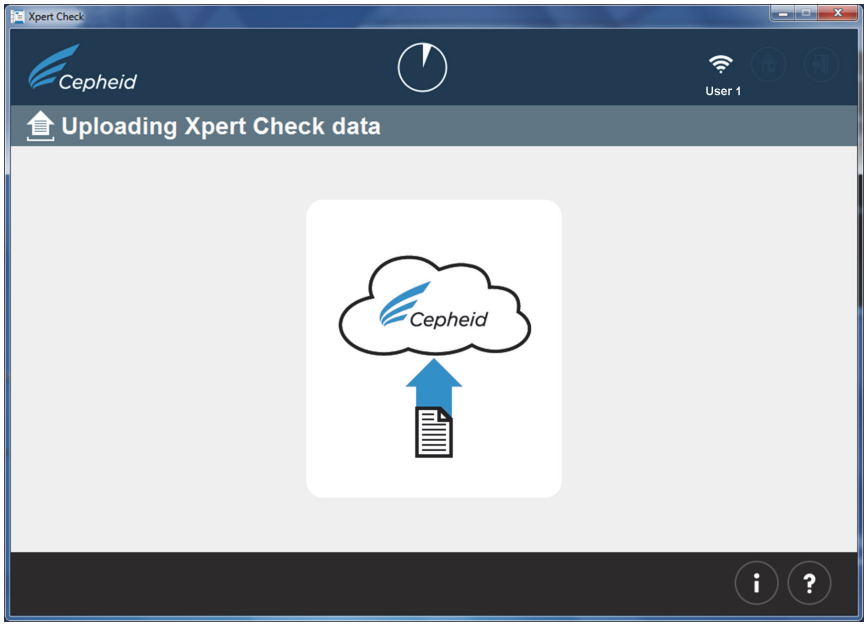


Figure 2-22. Uploading Xpert Check Data Screen

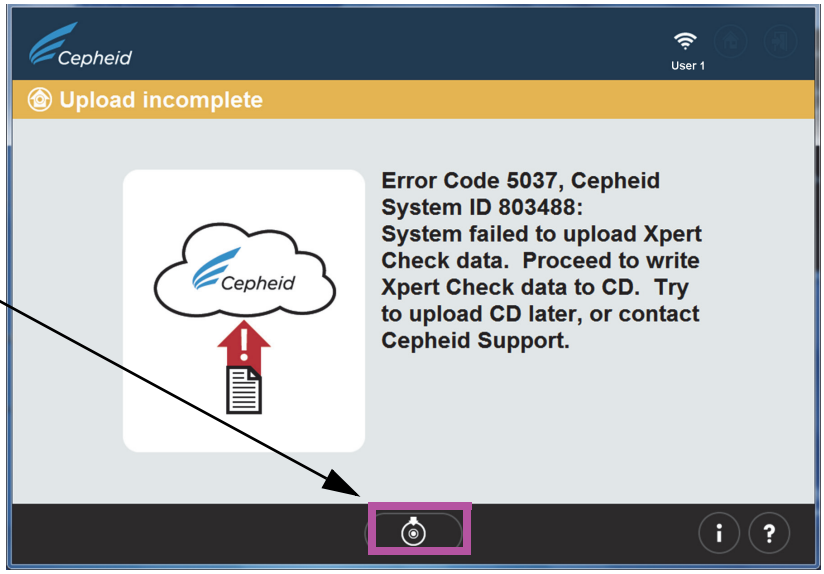


Figure 2-23. Upload incomplete Error Screen

21. When the Xpert Check data has finished uploading, a Quality Assurance check will be performed on the data. If the check is acceptable, the Xpert Check code will automatically download. See Figure 2-24.

    If the test is not acceptable, the affected module(s) will require service or replacement and will be flagged with an orange icon. Please contact Cepheid or your local ASP or the local Cepheid Technical Support office for further assistance.

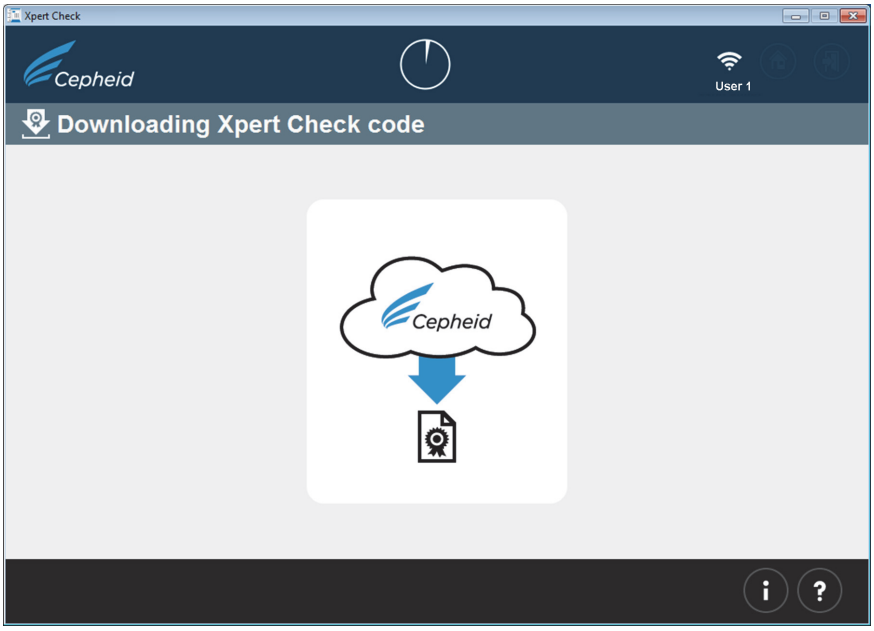


Figure 2-24. Downloading Xpert Check code Screen

22. After the Xpert Check test results have downloaded, the Xpert Check code will be applied to each successfully tested module, and those modules will then be identified with a **+** symbol. See Figure 2-25. As shown here, one module is being checked.

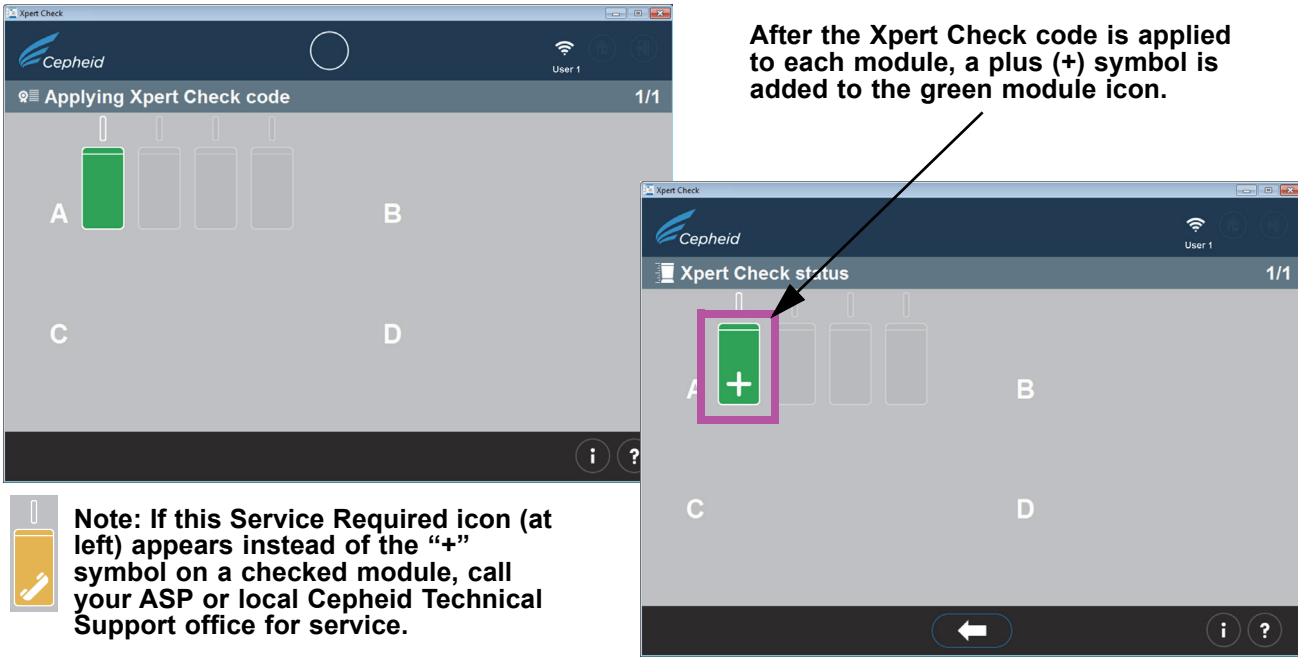


Figure 2-25. Applying Xpert Check code Screen

Note

In the screen shown in Figure 2-25, some modules may display the service required icon or may be grayed out if they were skipped.

23. After all the Xpert Check codes have been applied to the successfully-tested modules (those green modules which appear with the plus symbols applied), the Xpert Check complete screen will appear. See Figure 2-26. This screen shows the location of the Xpert Check Data report, which is available for review, if desired.

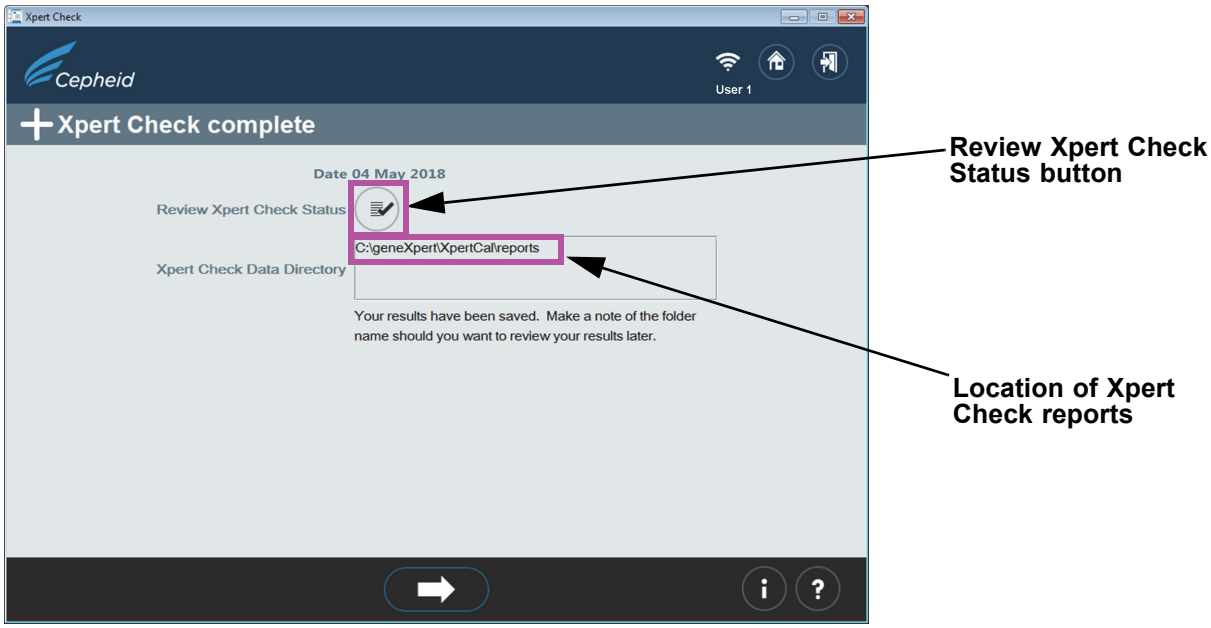


Figure 2-26. Xpert Check complete Screen

24. Remove and discard all Xpert Check cartridges. Do not save partial kits (all unused cartridges must be discarded).When complete, click the **Exit** icon at the top or bottom of the screen to exit the program. See Figure 2-27.

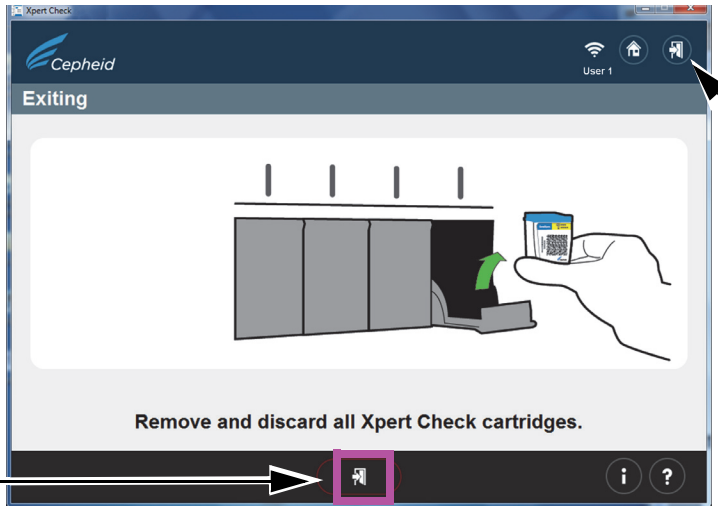


Figure 2-27. Exit the Program

25. The screen shown in Figure 2-28 appears only if you touch or click the exit arrow in the upper right of the screen.

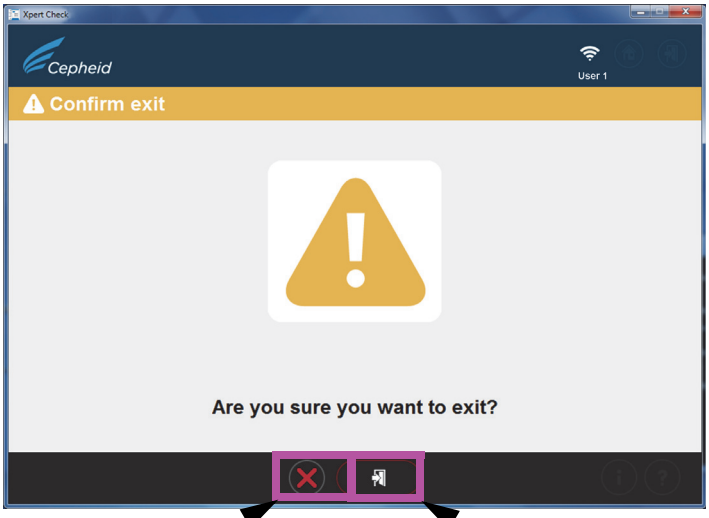


Figure 2-28. Confirm exit Screen

This completes the Xpert Check Test for an internet-connected user.

Note Contact your Authorized Service Provider or the local Cepheid Technical Support office concerning modules requiring service.

Note To view your Xpert Check results, see Step 23 and Figure 2-26, which shows the file path and location of Xpert Check results and the Xpert Check Summary report.

2.3.1 Xpert Check Completion For Non-internet Connected Users

For Non-internet connected users, you should have completed Step 1 through Step 19 of Section 2.3 to collect data before starting this section.

1. This section begins with the Data collection in progress screen, which is similar to Step 18 in Section 2.3, and the screen shown in Figure 2-18 for internet-connected users.

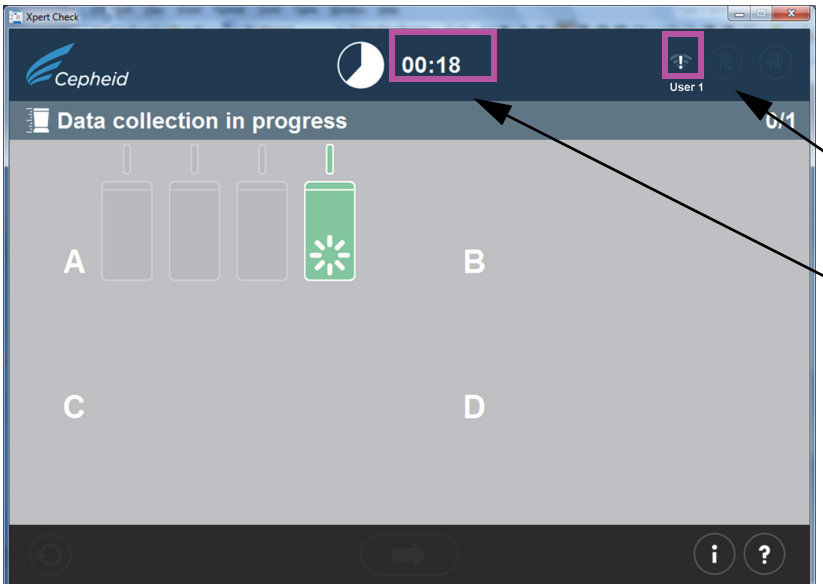


Figure 2-29. Data collection in progress Screen

2. After test completion, the module door will open and the light above the module will turn off. A screen similar to that shown in Figure 2-30 will appear. Touch or click the right arrow at the bottom of the screen to advance to the next screen.

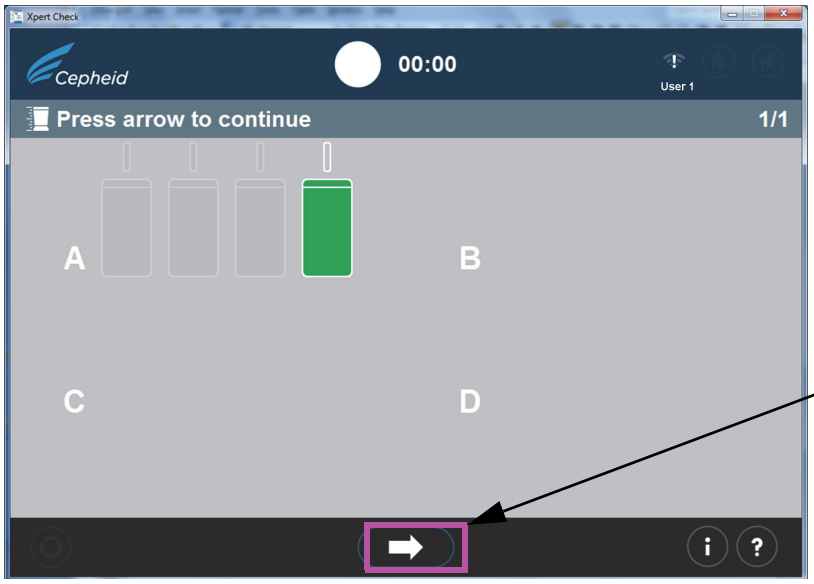


Figure 2-30. Test Completion screen - Successful

3. When the Write Xpert Check data to CD screen appears (Figure 2-31), you will be prompted to press the **Eject** button on the DVD drive to remove the existing Xpert Check Software CD so you can insert the blank data CD.

Note In the following step, use care in inserting the blank CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

Important **If you have been running this test as an internet-connected user and then lose your internet connection and received an error screen (Figure 2-23), resume your procedure beginning with the following Step 4, continuing through Step 12.**

Note In the following step, pause for 10 seconds after CD insertion and cancel any wizards that auto-open before touching or clicking the forward arrow to proceed. When you either close the wizard or have waited enough time to ensure that a wizard will not auto-open, touch or click the forward button to proceed. This will launch the Windows CD burning screens that the Xpert Check program opens.

4. Insert the blank CD into the DVD drive of the computer and close the DVD drive tray fully to ensure the CD will be recognized.

   Pause to allow the launch of any possible CD wizard programs. If wizard programs launch, close them before touching or clicking the forward button to proceed.

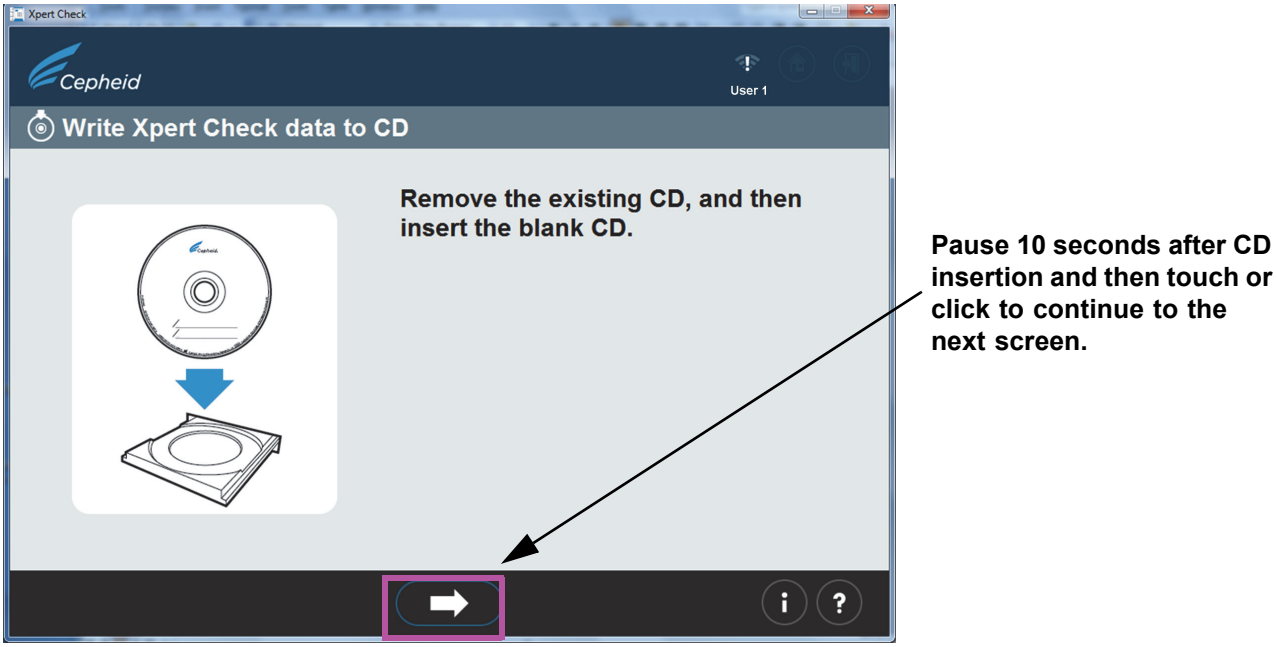


Figure 2-31. Write Xpert Check data to CD Screen - Step 1

5. After inserting the blank CD, the screen will change briefly, indicating the CD has been recognized. See Figure 2-32. This screen will remain displayed until the CD writing process is complete.

Note It is not necessary for the user to locate the file to write because that process is automatic.

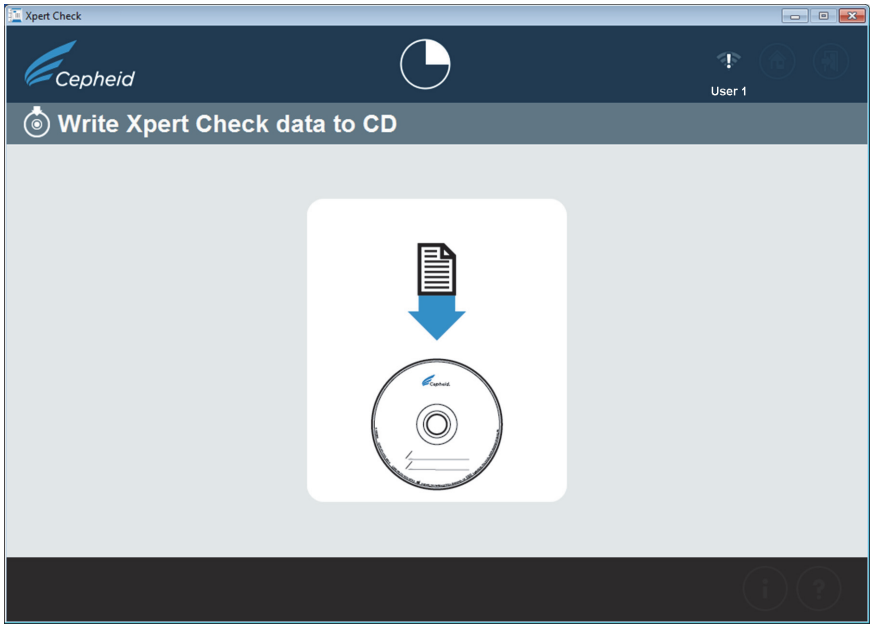


Figure 2-32. Write Xpert Check data to CD screen - Step 2

6. The CD Writing Wizard or Burn to Disc screen (Figure 2-34) will then appear as an overlay of the screen shown above, in Figure 2-32.

   The next screens (Figure 2-33 though Figure 2-37) show the CD writing program screens as you progress through the writing process.

   - Windows® 7 users: Follow the screens on the top of the figure.
   - Windows®10 users: Follow the screens at the bottom of the figure.

   A. On the first screen, after successful recognition of the blank CD, you will be asked to provide a name for the CD that you will be writing. DO NOT simply touch or click the **Next** button to continue the writing process with the default name that appears. Instead, type in your facility's name, such as "XYZ Hospital," in the space provided and touch or click **Next**. See Figure 2-33.

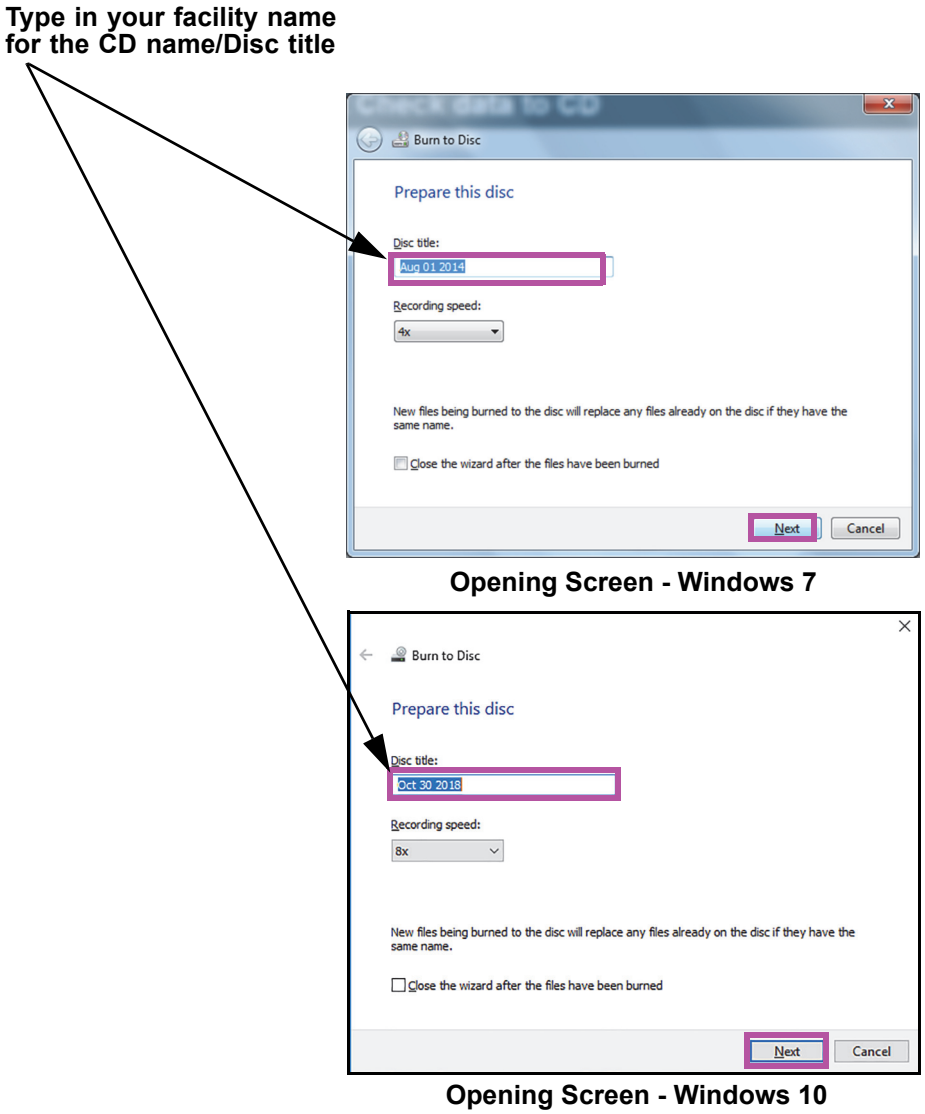


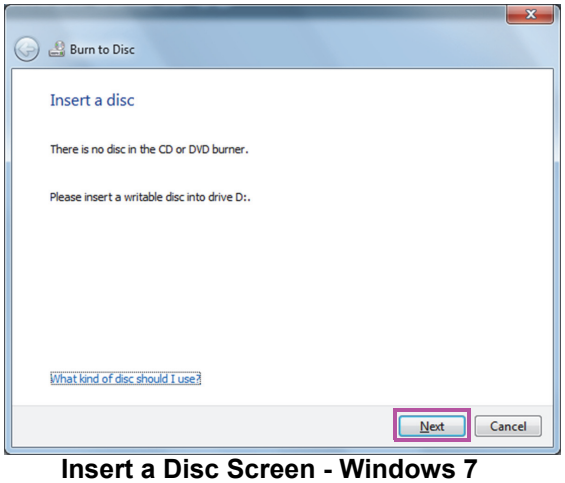
Figure 2-33. CD Writing Program - Opening Screen

B. If the CD is not recognized, the screen shown in Figure 2-34 may appear, instead of the screen in Figure 2-35, asking you to insert a writable disc to continue. Writable discs, in this case, are CDs on which you can store files. Writable discs can only be written to once, meaning that once any files are copied to the disc, they are there permanently.

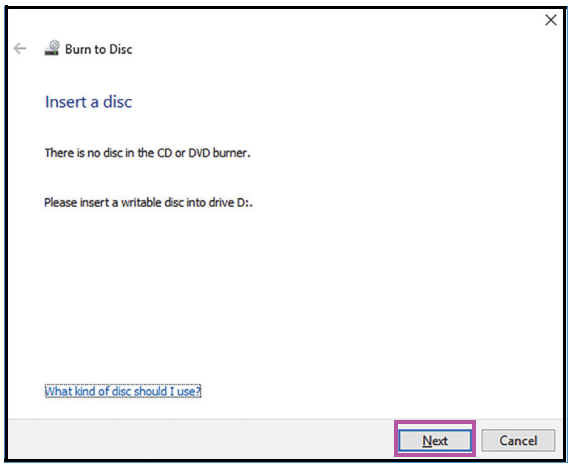
   A disc that has data on it is not considered to be a writable disc and will result in an error screen, as shown in Figure 2-39.

Note

If you are unsuccessful with any part of the CD writing process, you may contact your ASP or local Cepheid Technical Support office for assistance. It is safe for you to close the Xpert Check software now because the Xpert Check files have been saved to the hard drive and you will not lose data.



Insert a Disc Screen - Windows 7

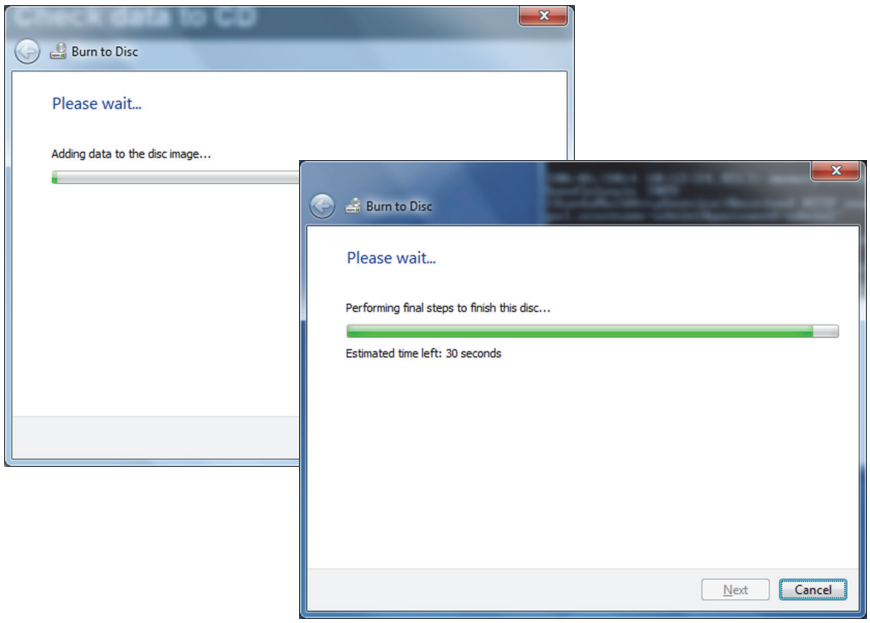


Insert a Disc Screen - Windows 10

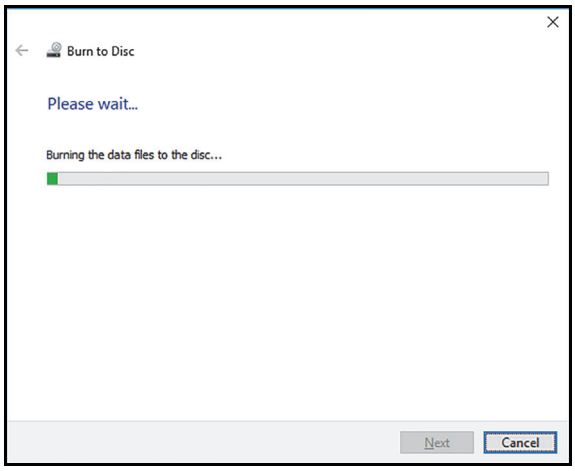
Figure 2-34. CD Writing program - Insert a writable disk to continue Screen - Example

C. After successful recognition and naming of the CD, touch or click the **Next** button to continue. The writing process will begin automatically.

D. During the writing/burning process, a progress bar will appear on the screen. See Figure 2-35.



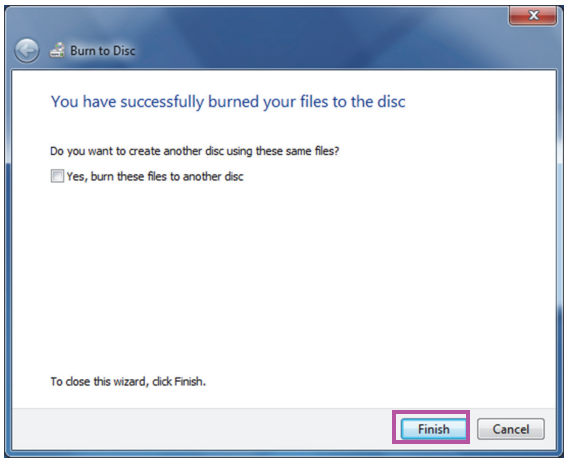
File Burning Progress Screens - Windows 7



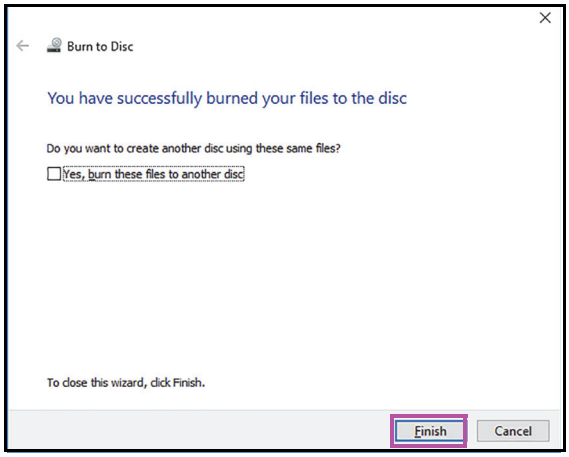
File Burning Progress Screen - Windows 10

Figure 2-35. CD Writing/Burning Progress Screen

E. When the writing of the CD is complete, the screen shown in Figure 2-36 will appear. Touch or click the **Finish** button to exit the CD writing program.



Completion Screen - Windows 7



Completion Screen - Windows 10

Figure 2-36. CD Writing Completion Screen

F. On a Windows 7 computer, you may see the screen displayed in Figure 2-37 after a successful CD write. Touch or click the **OK** button as many times as necessary for the screen to disappear, before continuing.

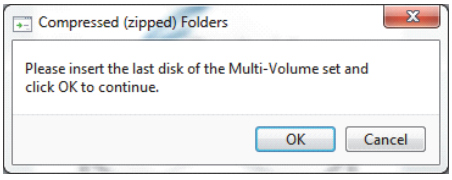
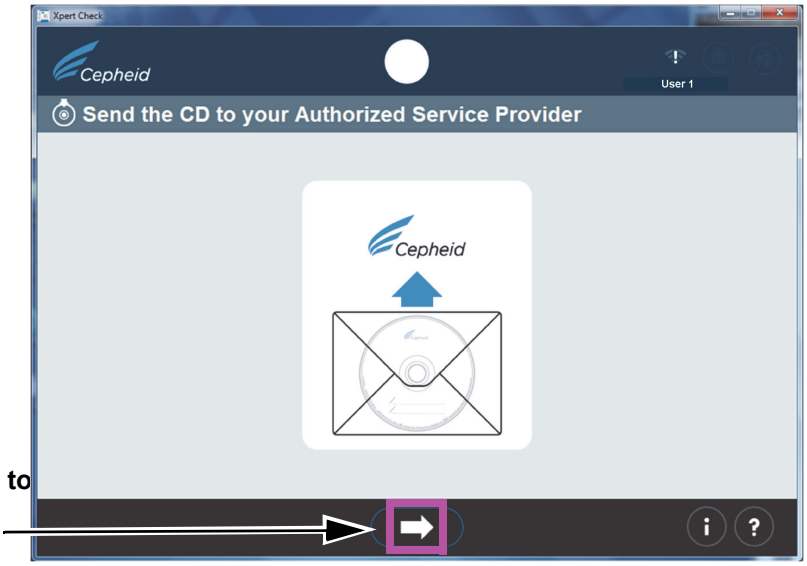


Figure 2-37. Final Screen from Windows 7 After CD Writing has Completed

7. After touching or clicking the **Finish** button on the CD writing screen, the Send the CD to your Authorized Service Provider Screen will appear (see Figure 2-38). Remove the completed Xpert Check data CD from the disk drive and prepare the label, as described in Step 10.



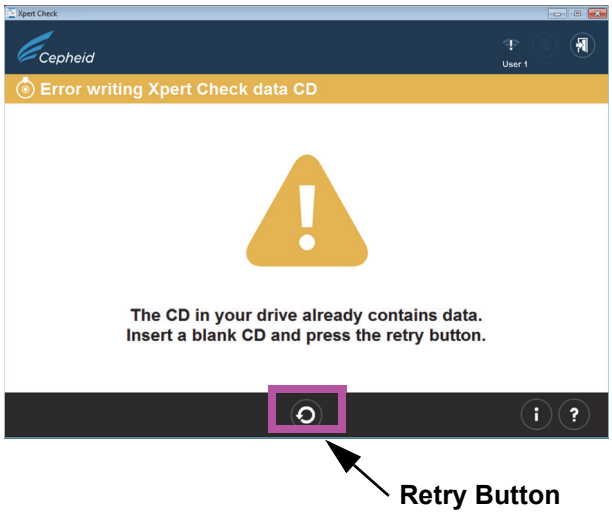
Touch or click to proceed to the next screen, prior to shutdown.

Figure 2-38. Send the CD to your Authorized Service Provider Screen - Step 3

8. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See Figure 2-39).

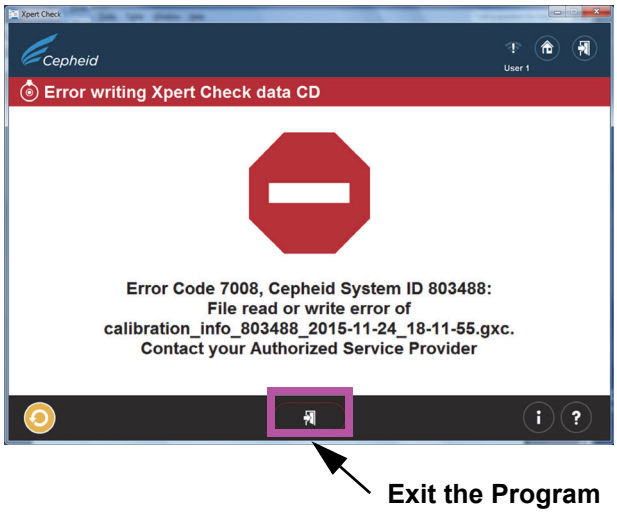
   - If a CD you have inserted already contains data as shown in the error screen below at the left, remove the CD and insert a blank CD, and then touch or click the **Retry** icon.
   - In the case of a read or write error, the screen shown at the right may appear and you must exit the program. Contact your ASP or the local Cepheid Technical Support office for assistance, if necessary.

Disc is not Writable (Already Contains Data)



Retry Button

General Write Failure



Exit the Program

Figure 2-39. Error writing Xpert Check data CD Screens - Two Examples

9. After test completion, the Exiting screen will appear with the message **Remove and discard all Xpert Check cartridges** (see Figure 2-40).

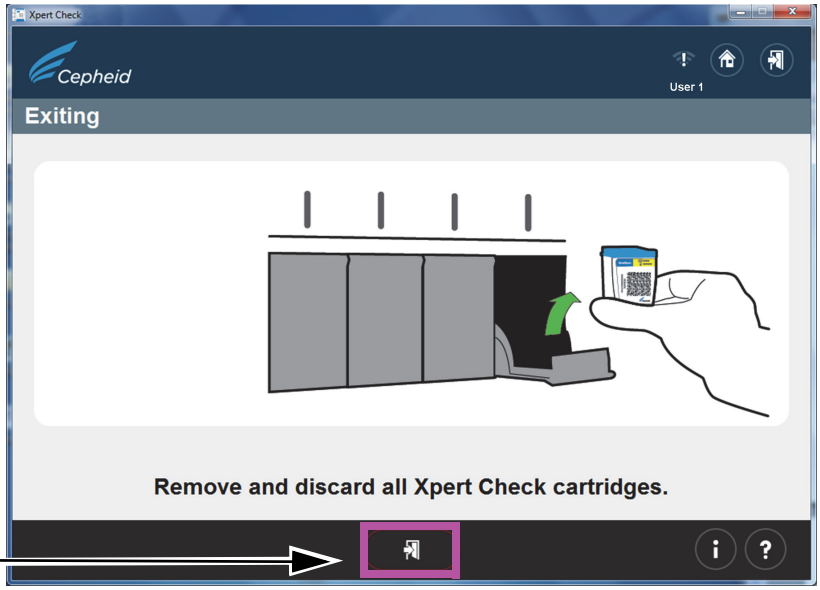
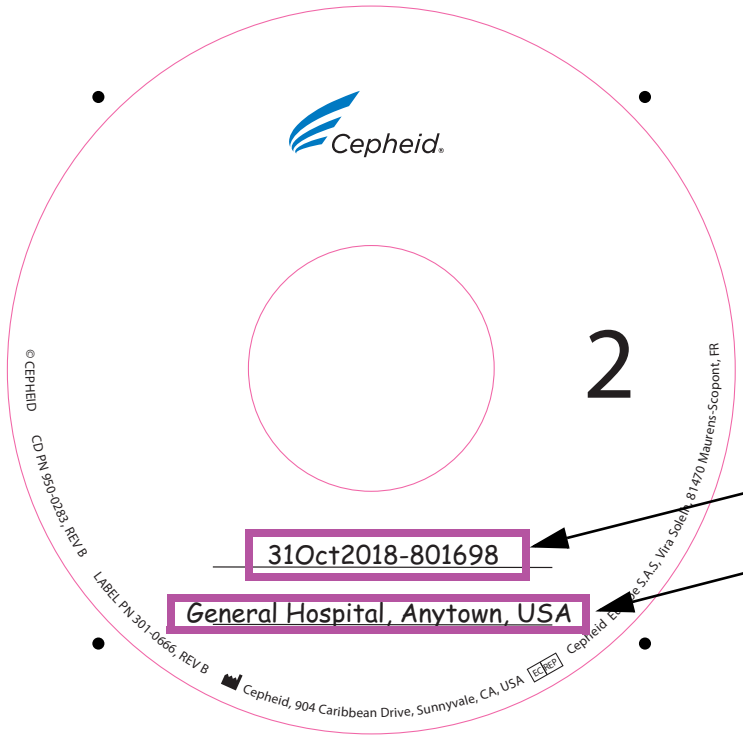


Figure 2-40. Exiting Screen

10. Use a felt-tip pen to write on the label of the Xpert Check data CD you have just created by writing the date, instrument identification and facility/location of the test performed. See a label example in Figure 2-41.



Note: It is the responsibility of the user to properly enter the date, instrument identification, facility name and location on the Data CD label.

Failure to properly label your Data CD may result in lost data and a delay in obtaining your module Xpert Check code test.

Date-Instrument Identification

Facility, Location

Figure 2-41. Data CD Labeling Example

11. You have the option to copy the calibration_info.gxc data file (located on the Xpert Check data CD just written) and Email the data file directly to your ASP or the local Cepheid Technical Support office instead of mailing the CD. If Email is not an option, place the Xpert Check CD2 into the provided CD shipping envelope and mail it to your local Authorized Service Provider (ASP) or the local Cepheid Technical Support office for data quality assurance checking and the issuing of your Xpert Check code.
12. Your ASP or the local Cepheid Technical Support office will perform the quality assurance review and, if successful, send back your Xpert Check code either by Email or regular mail, depending on what method you have previously set up with them.

Note Discard all remaining materials from the kit. DO NOT save unopened kit pouches for later use. DO NOT discard your Software CD. For users who Emailed their file and have not shipped their data CD: DO NOT discard your Data CD.

13. Restart your GeneXpert Dx, GeneXpert Xpress or Infinity system and computer.

Note You can continue to use your system while awaiting your Xpert Check code.

2.3.2 Obtaining the Xpert Check Code for Non-Internet Connected Users

Note Ensure the system is in the same configuration as when Xpert Check was run (i.e., no software updates or changes have been made and no new GeneXpert systems have been moved to or from this computer). In the case of any module servicing and/or replacement that may occur between data collection and application of the Xpert Check Code, new or modified modules will be ignored for the purposes of the Xpert Check testing process.

Note In the following step, use care in inserting the CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

1. Exit the GeneXpert Dx, GeneXpert Xpress or Infinity software.
2. To finish the Xpert Check process, place the Software CD in the DVD drive of the computer connected to the GeneXpert Dx or GeneXpert Xpress instrument or in the kiosk computer for the Infinity.
3. Touch or click on My Computer, then touch and hold or double-click on the applicable drive letter for your DVD drive. The files located on the CD will then be displayed. Find and touch and hold or double-click the **XpertCheck.exe** application/ shortcut to launch the software.
4. Log in with your GeneXpert Dx, GeneXpert Xpress or Infinity designated **USER NAME** and **PASSWORD** (see the IMPORTANT note in Section 2.1). Also see Figure 2-4 for the Login screen.

   After entering your login information, touch or click the forward arrow button at the bottom of the screen to advance to the next screen (the Xpert Check Home screen).

Note

The user name and password are the same ones you used for the GeneXpert Dx, GeneXpert Xpress or Xpertise software. If an ASP (FSE) previously performed Xpert Check and is not now on site, the user name and password should have been provided for this step to enter the code. If the user name or password are not now available, contact your ASP or your local Cepheid Technical Support office.

5. Touch or click the **Enter Xpert Check Code** button. See Figure 2-42. The Enter Xpert Check code screen will appear. See Figure 2-43.

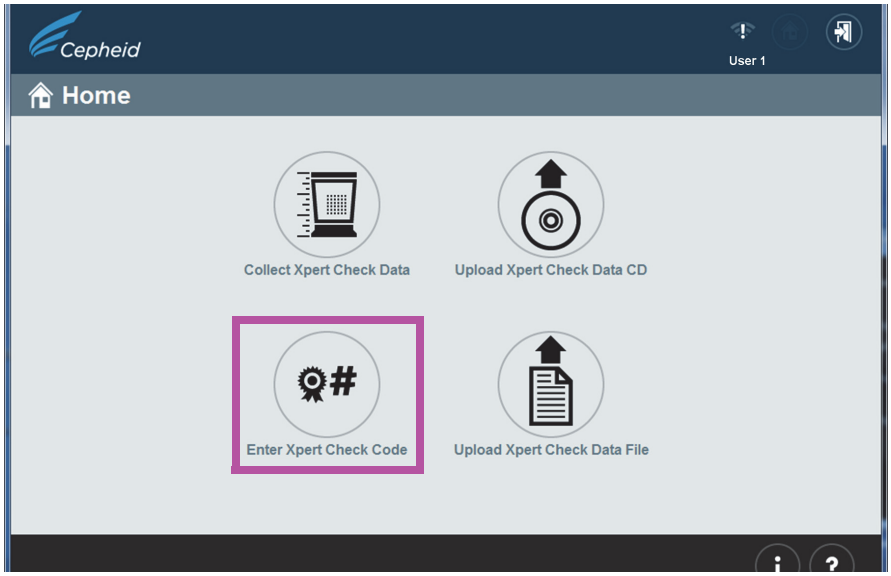


Figure 2-42. Home Screen, showing Enter Xpert Check Code Button

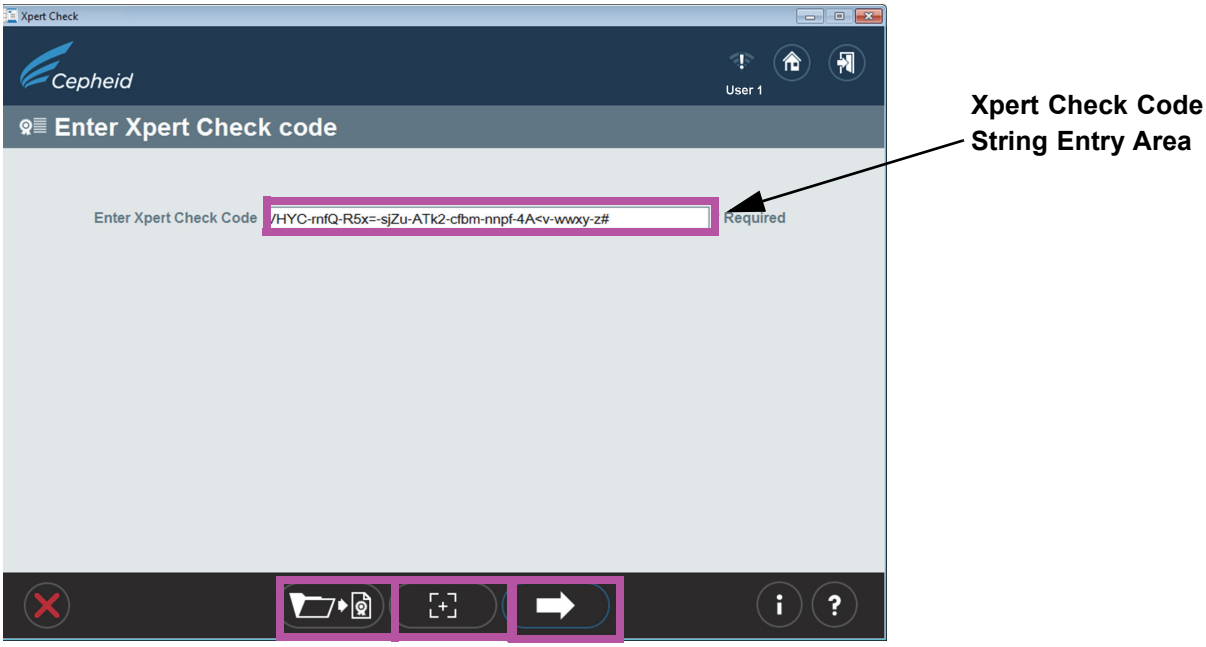


Figure 2-43. Enter Xpert Check code Screen

6. Enter your Xpert Check code as described below.

   In this step, there are various ways to enter the Xpert Check code, depending on your system. Your four options are listed below.

   A. Option 1 (For GeneXpert Dx or Infinity systems only): Use your scanner to input the barcode as follows: First, click the icon located in the bottom center of the screen. The Xpert Check Code File (Figure 2-44) will appear on your screen. Position your scanner to scan the barcode on the Code form, using care to avoid any reflection on the monitor that may interfere with your scanner. See Figure 2-44 for an example of an Xpert Check Code File.

   B. Option 2 (For all systems): Print a copy of the Xpert Check Code File and use your scanner to scan the barcode on the printed page. See Figure 2-44 for an example of an Xpert Check Code File.

   C. Option 3 (For GeneXpert Dx and Infinity systems only): Copy and paste the code string into the Enter code screen from the screen's display. The code string is visible on Figure 2-44.

   D. Option 4 (For all systems): Type in the code string manually using the information on your screen or printed page.

   When you have successfully entered the code, touch or click the forward arrow at the bottom of the screen to continue. The Applying Xpert Check code screen will appear. See Figure 2-45.

Cepheid®

Xpert Check Code File

Here is the Xpert Check code for the recent data collection of your modules for the system identified below.

Xpert Check data collection performed on 30 September 2020 15:02:31 PST

GX Instrument Name:	My GeneXpert
Cepheid System ID:	123456
Software Version:	Xh1.5a
Data Collected By:	admin1
Institution Name:	Institution1
Laboratory Name:	Lab1
Street Address:	100 Main Street, Suite 202
City:	New York
State/Province:	NY
Postal Code:	10001
Country:	USA
Email:	user@institution.com
Facility Phone Number:	408 400-0000
Extension:	
Mobile:	
ASP Code:	US01

Scan or enter the Xpert Check code to complete the Xpert Check process.

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.

2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

GeneXpert® Xpert Check Version: Xh1.5a

Page 1 of 1

Figure 2-44. Xpert Check Code File - Example

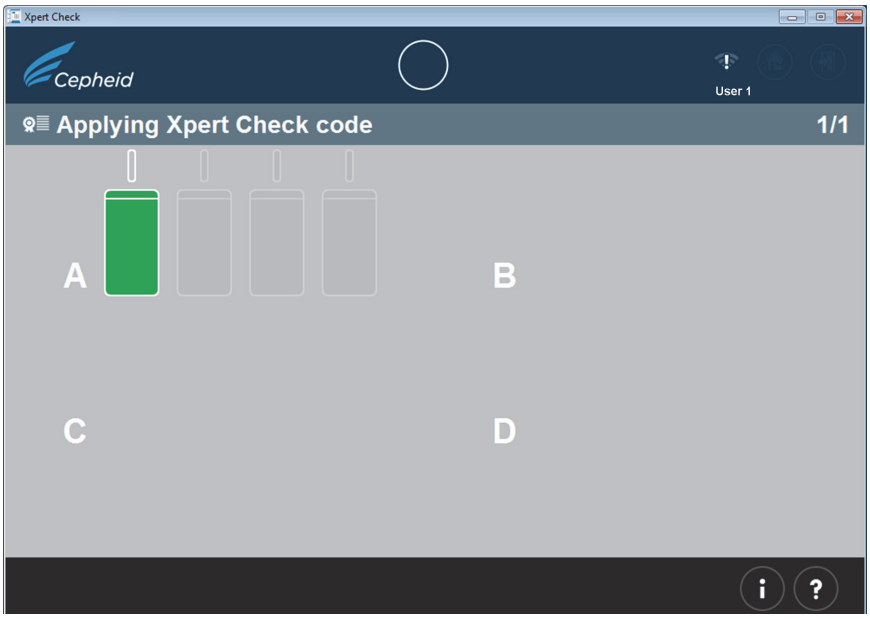


Figure 2-45. Applying Xpert Check code Screen Example

E. After the Xpert Check code has been applied, the Xpert Check Complete screen will appear with the location of the Xpert Check Report displayed in the **Xpert Check Data Directory** area. Write down the file path and location of the Xpert Check Report file, as shown. See Figure 2-46.

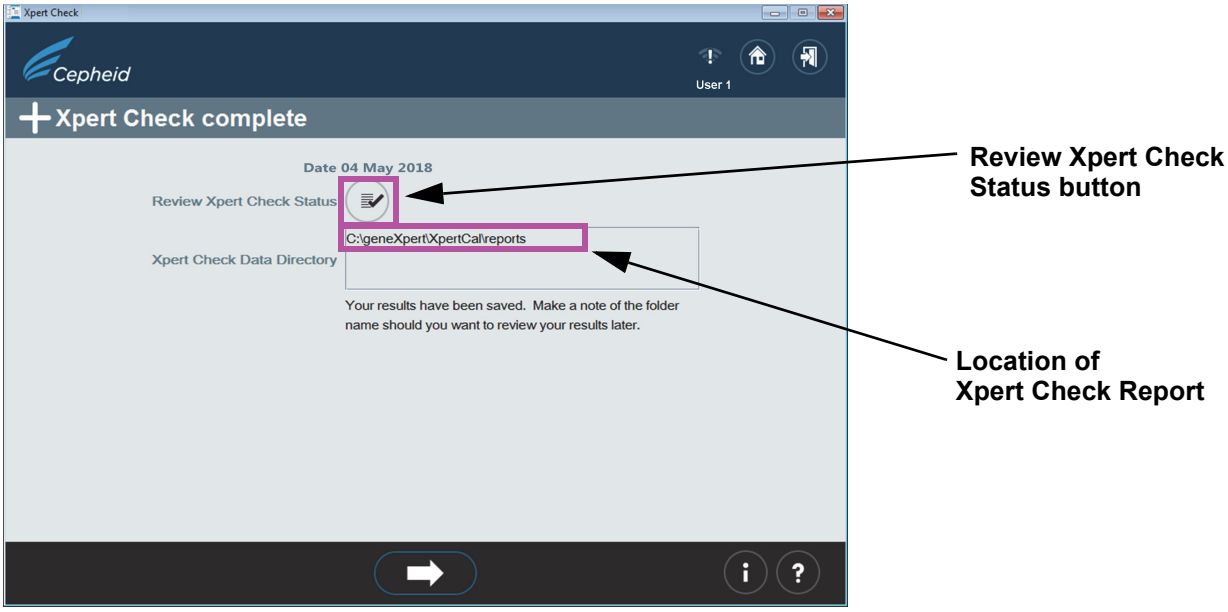


Figure 2-46. Xpert Check complete Screen

F. Touch or click the **Review Xpert Check Status** button (see Figure 2-46).

G. The Xpert Check status screen will appear. See Figure 2-47. In the Xpert Check status screen, the successfully checked modules are indicated by a **+** symbol on a green module.

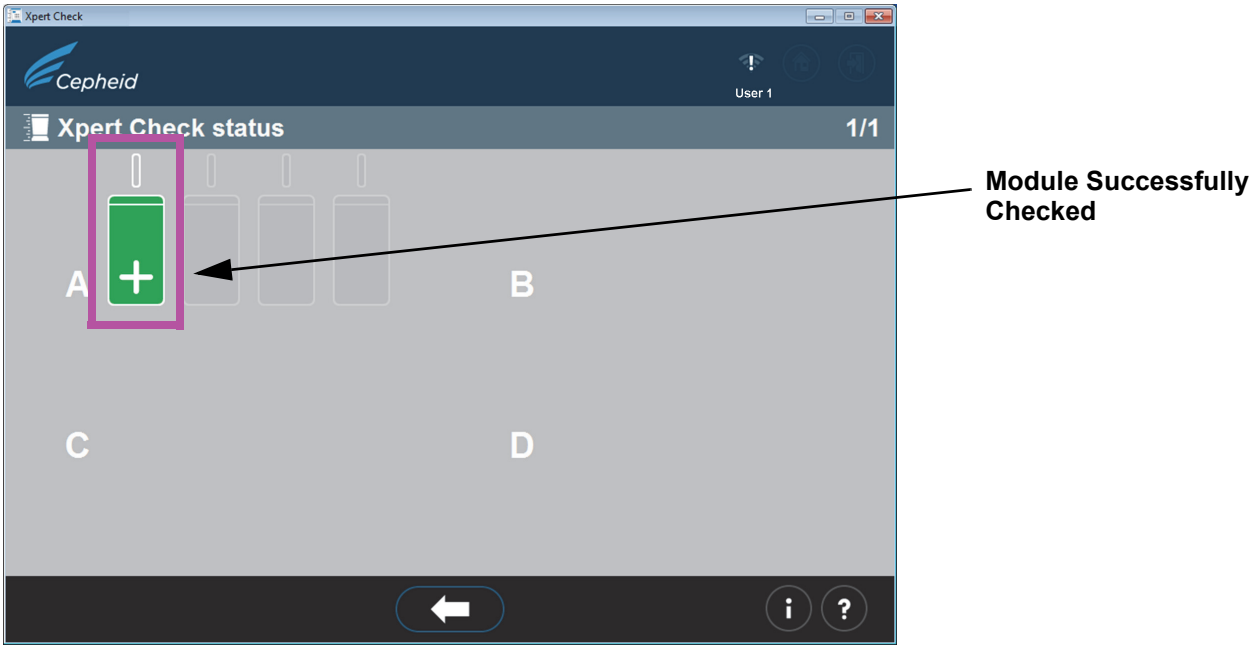


Figure 2-47. Xpert Check status Screen

Note

If the Xpert Check report on the computer has been deleted, contact your ASP or the local Cepheid Technical Support office for assistance.

7. Identify the generated Xpert Check Report file in the folder **C:\GeneXpert\XpertCal\Reports**.

8. Identify the generated Xpert Check Summary Report file in the folder **C:\GeneXpert\XpertCal\Reports**.

   A. See Figure 2-48 for an example of a Xpert Check Summary Report.

   The Xpert Check Summary Report lists the modules that had an unsuccessful test and require retesting or service.

   The modules requiring retesting or service are listed by serial number in Table 1 on the form in Figure 2-48. When requesting service, provide these listed serial numbers to your ASP or the local Cepheid Technical Support office.

   Gateway information is provided in Table 2 of the form.

Cepheid

Xpert Check Summary Report

Please Note:

Xpert Check data collection performed on 30 September 2020 09:37:04 PDT
All modules that DID NOT pass Xpert Check are listed in Table 1: Modules Requiring Service.
Gateway Informations are provided in Table 2.
Complete test results for each module are listed in Table 3: Detailed Test Results by Module.

GX Instrument Name:	My 6Color
Cepheid System ID:	12345
Data Collected By:	User1
Institution Name:	Institution1
Laboratory Name:	Laboratory Sunnyvale
Street Address:	123 Main Street
City:	Sunnyvale
State/Province:	CA
Postal Code:	90001
Country:	USA
Email:	User1@Institution1.com
Facility Phone Number:	408-400-XXXX
Extension:	
Mobile:	
ASP Code:	US03

Table 1: Modules Requiring Service

Module Serial Number / Location	Module Status
639563/A2	Skipped and Retest required
639565/A1	Requiring Service

Table 2: Gateway Information

Gateway Serial Number	MAC Address
804471	00:21:38:00:2E:1B
804470	00:21:38:00:2E:1A

Figure 2-48. Xpert Check Summary Report Example - Page 1

Cepheid®

Xpert Check Summary Report

Table 3: Detailed Test Results by Module Serial Number

The column header will show Module Serial Number, followed by (Location / Cartridge Lot).

If a module undergoes multiple tests, the Module Serial Number will be shown as Module Serial Number : Cartridge -Test Run.

Test	639565 (A1/00402)
Cartridge Load	pass
Module Tests	pass
Ambient Temperature	pass
Motherboard EEPROM	pass
ICORE EEPROM	pass
+12V Power Supply	pass
-12V Power Supply	pass
+24V Power Supply	pass
Valve Drive	pass
Valve Label Dropouts	pass
Valve Home Integrity	pass
Valve Timing	pass
Valve Drift	pass
Pump Drive	pass
Ultrasonic	pass
ICORE Heater	pass
ICORE Fan	pass
Force Sensor	pass
Optical Check	fail
EBF Value	pass
Probe Check	fail

1. Cepheid recommends that system performance should be evaluated annually using Xpert Check.

2. Cepheid declares that the I-CORE modules in the GeneXpert® Instrument were checked using an Xpert Check product. NIST traceable qualification standards are used to control the parameters for the fluorescence standards of concentration, brightness, and spectrum. Cepheid products are manufactured, quantified and controlled under a Quality System compliant with ISO 13485 and QSR requirements.

GeneXpert® Xpert Check Version: Xh1.5a

Page 2 of 2

Figure 2-49. Xpert Check Summary Report Example - Page 2

2.4 Return System to Normal Operation

Note Return the system to normal operation by following one of the three procedures listed in this section for the GeneXpert Dx, GeneXpert Xpress, the Infinity-48, the Infinity 48s, or the Infinity-80.

2.4.1 GeneXpert Dx

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Dx.

1. Restart your GeneXpert system and computer. Follow the instructions in the GeneXpert Dx System Operator Manual.
2. The system will be ready for full operation.

2.4.2 GeneXpert Xpress

Ensure all Xpert Check cartridges and CDs have been removed from the GeneXpert Xpress.

1. Restart your GeneXpert Xpress system. Follow the instructions in the GeneXpert Xpress User's Guide.
2. The system will be ready for full operation

2.4.3 Infinity-48

Ensure all Xpert Check cartridges and CDs have been removed from the Infinity-48.

1. Restart the Xpertise software and switch the system from Manual mode back to Automation mode. Follow the instructions in the GeneXpert Infinity System Operator Manual for the Infinity-48.
2. The system will be ready for full operation.

2.4.4 Infinity-48s or Infinity-80

Ensure all Xpert Check cartridges and CDs have been removed from the Infinity-48s or Infinity-80.

1. Restart the Xpertise software. Follow the instructions in the GeneXpert Infinity System Operator Manual.

The system will be in Automation mode, ready for full operation.

2.5 Information Key Screen

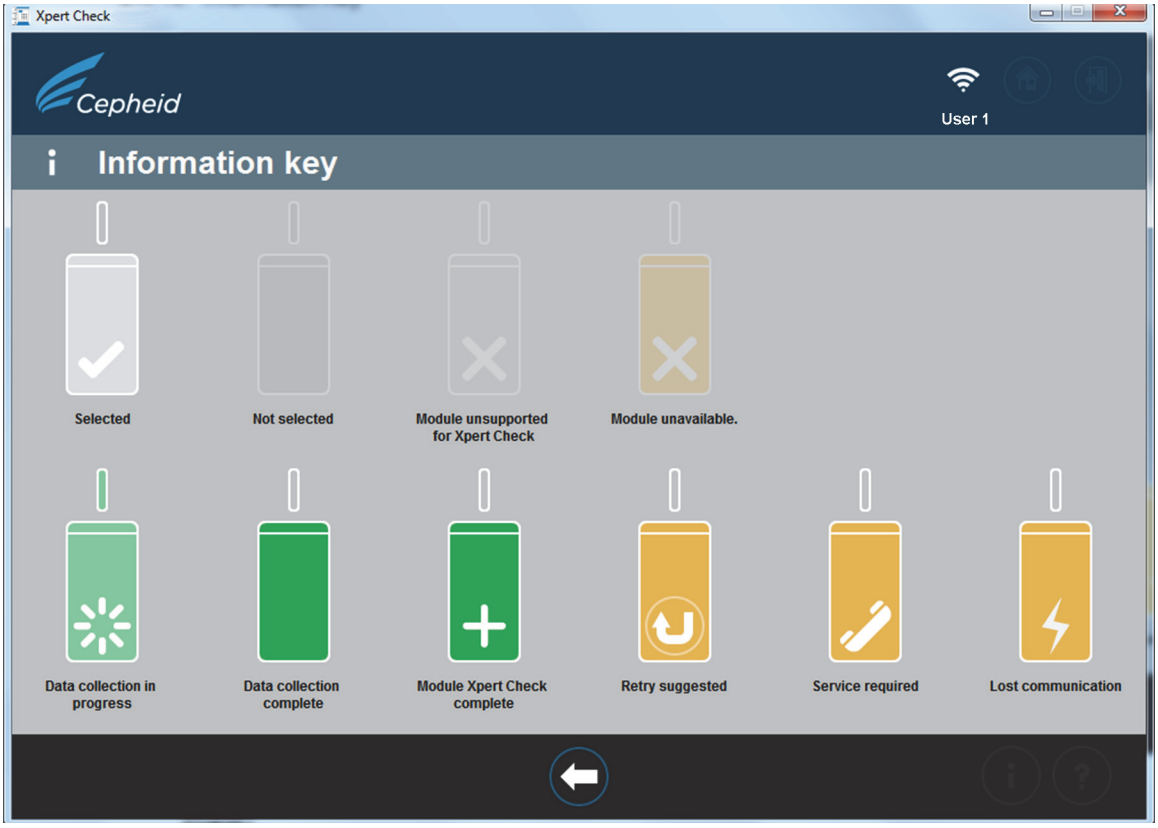


Figure 2-50. Information key Screen

2.5.1 Reasons to Repeat Xpert Check with a New Cartridge

If the onscreen instructions direct you to retest, repeat the test according to the instructions in Step B. on page 2-19.

2.5.2 Reasons to Repeat Xpert Check with the Same Cartridge

If software reports that the cartridge film seal was not broken, remove the original cartridge, rescan the cartridge barcode, open the lid, close the lid, and reinsert the cartridge. Restart the Xpert Check procedure for the affected module.

2.5.3 Application of Xpert Check Code

Xpert Check is not complete until the Cepheid-supplied Xpert Check code is applied to the system being tested. Upon receipt of the Quality Assurance Xpert Check Code from Cepheid, apply the code to your system using the Xpert Check Software to complete the Xpert Check process.