

Anexa nr. 7
la Documentația standard nr. _____
din “___” _____ 20__

CERERE DE PARTICIPARE

Către CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE

Stimați 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-1662560844952 din 07/09/2022, privind aplicarea procedurii pentru atribuirea contractului privind Achiziționarea testelor și consumabilelor întru realizarea Programului Național de combaterea hepatitelor virale B, C și D pentru anul 2023, 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 24.10.2022

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel

ORDIN DE PLATA NR.478

Tip.doc. 1 :

DATA EMITERII: 11 octombrie 2022

PLATITI:65710-52

LEI: Sasezeci si Cinci Mii Sapte Sute Z :
ece, 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 P CODUL IBAN:MD23TRPCCC518430B01859AA :
UBLICE CENTRALIZATE IN SANATATE CODUL FISCAL:1016601000212 :

PRESTATORUL BENEFICIAR

Min.Finantelor-Trezoreria de Stat

DESTINATIA PLATII: /P102/65710,52 Garantia pentru :
oferta in valoare de 2 procente, pentruprocedura de: NORMAL/URGENT:NO :
achizitie publica nr.MTender ID ocds-b3wdp1-MD-166: :
25608 :
:

L.S.

CODUL TRANZACTIEI:101

DATA PRIMIRII:

DATA EXECUTARII:

SEM NATURILE

EMITENTULUI

SEM NATURA PRESTATORULUI

MOTIVUL REFUZULUI



13:31:55 11 OCT 2022

Semnatura electronica:

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ORDIN DE PLATA NR.497 Tip.doc. 1 :

DATA EMITERII: 27 octombrie 2022 :

PLATITI:8386-35 LEI: Opt Mii Trei Sute Optzeci si Sase, 35 :

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI02224260000269MDL:
CODUL FISCAL:1018600004516 :

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

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

PRESTATORUL BENEFICIAR
Min.Finantelor-Trezoreria de Stat :

DESTINATIA PLATII: /P102/8386,35 Garantia pentru o :
ferta la LP nr. ocds-b3wdp1-MD-1662560844952 din 07: NORMAL/URGENT:NO :
.09.2022. (ID 21063111) :

L.S.

CODUL TRANZACTIEI:101 :

DATA PRIMIRII: : _____ :

DATA EXECUTARII: : _____ :

: SEMNATURILE :
: EMITENTULUI :

SEMNATURA PRESTATORULUI :

MOTIVUL REFUZULUI :



16:41:48 27 OCT 2022

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VICTORIABANK
PRIMA BANCĂ DIN MOLDOVA



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 " ianie 2018

La Nr. 395 din " 19 " ianie 2018

Secret bancar
Confidențial

CERTIFICAT

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

MD57VI022242600000269MDL;
MD76VI022242600000105USD;
MD61VI022242600000116EUR;
MD83VI022242600000008RON.

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

Cebanu Valentina
Director



Blanovscaia Anna
Contabil-șef

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

VICTORIABANK

DECLARAȚIE
privind valabilitatea ofertei

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

Stimați domni,

Ne angajăm să menținem oferta valabilă, **privind Achiziționarea testelor și consumabilelor întru realizarea Programului Național de combaterea hepatitelor virale B, C și D pentru anul 2023**, pentru o durată de 160 zile, (una sută șase zeci), respectiv până la data de 30/04/2023 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 24.10.2022

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

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 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.

- termenul de valabilitate restant va constitui nu mai puțin de 80% din termenul total al produsului.

- bunurile ce urmează a fi achiziționate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale, mai jos dovada:

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr.	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
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	XPRTCHECK-CE-5	SUA	CEPHEID	MEDIST GRUP S.R.L.	A07.PS-01.Rg04-91	05-04-2019

Data: 24.10.2022

MEDIST GRUP S.R.L.
DIRECTOR
GABRIELA ANGHEL

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2021 - 31.12.2021

Entitatea: MEDIST GRUP S.R.L.

Cod CUIŢO: 41247072

Cod IDNO: 1018600004516

Sediul:

MD:

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: 24, Proprietatea cetătenilor străni, a persoanelor juridice si a persoanelor fără cetătenie

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: 068681147

WEB:

E-mail: natalia.mutu@medist.md

Numele și coordonatele al contabilului-șef: DI (dna) Mutu Natalia 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

BILANȚUL

la 31.12.2021

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	1927	
	din care:			
	2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023	1927	
	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	1927	
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	1112754	1673086
	din care:			
	3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	1103416	1657741
	3.4. mijloace de transport	084		

A.

3.5. inventar și mobilier	085		
3.6. alte mijloace fixe	086	9338	15345
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	35992	141992
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	1148746	1815078
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	1150673	1815078

B.

ACTIVE CIRCULANTE			
I. Stocuri			
1. Materiale și obiecte de mică valoare și scurtă durată	240	42145	32816
2. Active biologice circulante	250		
3. Producția în curs de execuție	260		
4. Produse și mărfuri	270	1838458	2084205
5. Avansuri acordate pentru stocuri	280		
Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	1880603	2117021
II. Creanțe curente și alte active circulante			
1. Creanțe comerciale curente	300	943191	745255
2. Creanțe ale părților afiliate curente	310		
inclusiv: creanțe aferente intereselor de participare	311		
3. Creanțe ale bugetului	320	266004	192050
4. Creanțele ale personalului	330		
5. Alte creanțe curente	340	701053	2484163
6. Cheltuieli anticipate curente	350	44875	13622
7. Alte active circulante	360	13806	12373
Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	1968929	3447463
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	415167	3083838
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	4264699	8648322
	TOTAL ACTIVE (rd.230 + rd.420)	430	5415372	10463400
	P A S I V			
	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 precedenți	560	-3139465	-3139465
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	7715649
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	-3139465	4576184
	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	-2766439	4949210
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640	3353966	2293001
	din care:	641		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643	3353966	2293001
	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	3353966	2293001
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720	1468158	1965429

	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	1468158	1965429
	3. Datorii comerciale curente	730	1301947	22996
E.	4. Datorii față de părțile afiliate curente	740	1711371	15427
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	341964	479003
	6. Datorii față de personal	760	55	
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	4350	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	4827845	3221189
	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
F.	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	5415372	10463400

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2021 până la 31.12.2021

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	12381902	33578934
din care:			
venituri din vânzarea produselor și mărfurilor	011	11478666	33233405
venituri din prestarea serviciilor și executarea lucrărilor	012	249374	93698
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	653862	251831
Costul vânzărilor, total	020	9837770	21572504
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	9837770	21572504
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	2544132	12006430
Alte venituri din activitatea operațională	040	1839	34729
Cheltuieli de distribuire	050	38549	309807
Cheltuieli administrative	060	2605584	3316071
Alte cheltuieli din activitatea operațională	070	176866	430627
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	-275028	7984654

Venituri financiare, total	090	323541	1154867
din care:	091		
venituri din interese de participare			
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	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	323541	1154867
Cheltuieli financiare, total	100	828557	685067
din care:	101	84503	
cheltuieli privind dobânzile			
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	744054	685067
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-505016	469800
Venituri cu active imobilizate și excepționale	120	384338	
Cheltuieli cu active imobilizate și excepționale	130	303272	
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140	81066	
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-423950	469800
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	-698978	8454454
Cheltuieli privind impozitul pe venit	170		738805
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	-698978	7715649

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2021 pînă la 31.12.2021

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul 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				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	-3139465			-3139465
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	7715649		7715649
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	-3139465	7715649		4576184
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	-2766439	7715649		4949210

SITUAȚIA FLUXURILOR DE NUMERAR

de la 01.01.2021 până la 31.12.2021

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010	13996800	36964792
Plăți pentru stocuri și servicii procurate	020	13833052	31765229
Plăți către angajați și organe de asigurare socială și medicală	030	1582458	1675720
Dobânzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060	1839	
Alte plăți	070	270627	490294
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	-1687498	3033549
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi 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	1283603	2042210
Plăți aferente rambursării creditelor și împrumuturilor	160		2474672
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	1283603	-432462
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-403895	2601087
Diferențe de curs valutar favorabile (nefavorabile)	220	-25931	67584
Sold de numerar la începutul perioadei de gestiune	230	844993	415167
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	415167	3083838

Recipisa

Respondent

Codul fiscal: 1018600004516, denumire: MEDIST GRUP S.R.L.

À prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2021

Data prezentarii: 27.05.2022

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 27.05.2022 09:39:42

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2221110**

din
от **25.10.2022**

1. Destinația / Назначение

pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
MEDIST GRUP S.R.L.	1018600004516
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Mitropolit Gavriil Banulescu-Bodoni nr.25 of.33	0120-SEC.BUIUCANI

3. 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.

4. Valabil pînă la / Действителен до 09.11.2022

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef Direcție

Sergiu CHIRCU

Funcția/Doljnost

Semnătura/Подпись

Numele și prenumele/Фамилия и имя

L.,Ș/ М.П.

Executor: C. Coșanu
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 25.10.2022 ora 12:02:58
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

**Extras
din Registrul de stat al persoanelor juridice
nr. 103268 din 06.10.2022**



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, str. Mitropolit Gavriil Bănulescu-Bodoni 25, ap. 33, mun. Chișinău, Republica Moldova**

Genurile de activitate:

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

Capitalul social: **373026 Lei**

Administrator(i): **ANGHEL GABRIELA-CRISTINA.**

Asociați:

- 1. "MEDIST IMAGING & P.O.C." S.R.L., partea socială 6244 Euro, ce constituie 33 %**
- 2. "MEDIST LIFE SCIENCE" S.R.L., partea socială 6244 Euro, ce constituie 33 %**
- 3. "MEDIST" S.R.L., partea socială 6433 Euro, ce constituie 34 %**

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 și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de 06.10.2022

Specialist coordonator

Aliona Lazari

tel. 022-207840




Lista fondatorilor operatorului economic

Subsemnata, **Gabriela Anghel**, reprezentant legal al **MEDIST GRUP S.R.L.**, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, oficiul 33, declar pe propria răspundere, că lista fondatorilor este compusă din următorii:

- MEDIST S.R.L., cod fiscal: RO 6705884
- MEDIST LIFE SCIENCE S.R.L., cod fiscal: RO 24205119
- MEDIST IMAGING & P.O.C. S.R.L., cod fiscal: RO 24205100

Data: 24.10.2022



MEDIST GRUP S.R.L.
DIRECTOARE ADMINISTRATIVĂ
GABRIELA ANGHEL

Xpert® HBV Viral Load

Simplify Hepatitis B Treatment Management



→ Quality Testing and
Flexibility for Any Setting

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 throughput 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



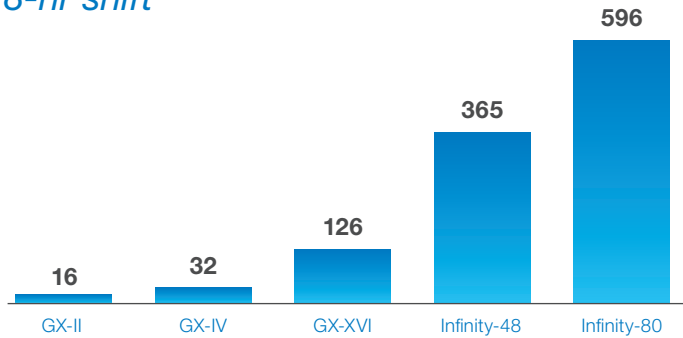
2

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.



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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www.Cepheidinternational.com

Xpert® HBV Viral Load

Упростите проведение лечения гепатита В

→ Качественное тестирование и
гибкость в любых условиях



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 В 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 В и С.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 В (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 В, 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



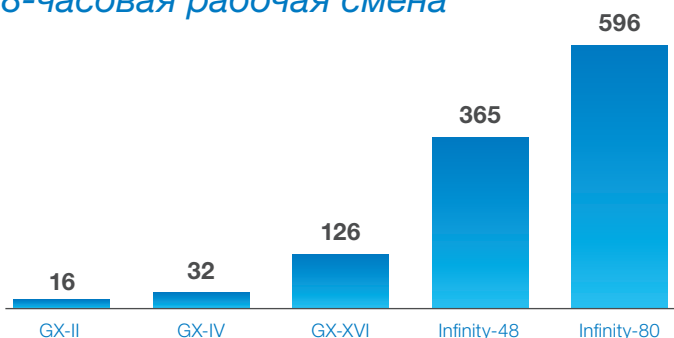
2

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.



КАТАЛОЖНЫЙ НОМЕР

Хpert® 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>

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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:

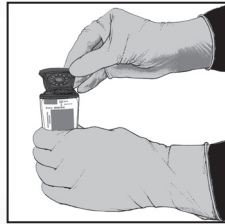
1. Centrifuge the sample to separate the plasma/serum and red blood cells per the manufacturer's instruction.
2. Equilibrate the plasma/serum to room temperature (20-35 °C).
3. Vortex for 15 seconds before use. If specimen is cloudy, clarify by a quick spin..



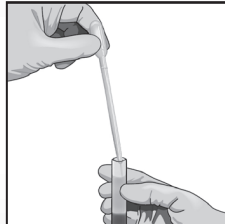
- 1 Take one Xpert cartridge for each sample.



- 2 Open the cartridge 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.

Xpert[®] HBV VL Cartridge Preparation

- Xpert[®] HBV Viral Load

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

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Prior to beginning this test:

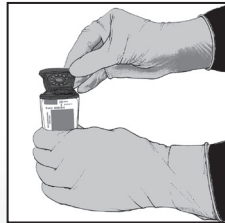
1. Centrifuge the sample to separate the plasma/serum and red blood cells per the manufacturer's instruction.
2. Equilibrate the plasma/serum to room temperature (20-35 °C).
3. Vortex for 10 seconds before use. If specimen is cloudy, clarify by a quick spin..



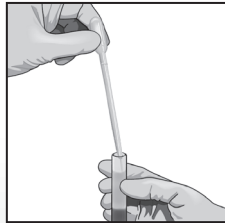
- 1 Take one Xpert cartridge for each sample.



- 2 Open the cartridge 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.

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:

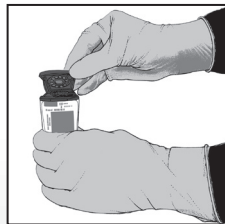
1. Отделите плазму/сыворотку от эритроцитов путем центрифугирования образца, следуя инструкциям изготовителя.
2. Дождитесь прогрева плазмы/сыворотки до комнатной температуры (20-35 °C).
3. Перед использованием выполните перемешивание на вихревой мешалке в течение 10 секунд. Мутный образец следует отцентрифугировать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



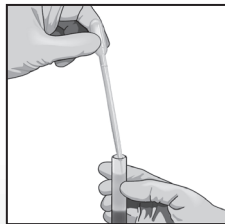
- 1** Возьмите по одному картриджу Xpert для каждого образца.



- 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.

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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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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**

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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

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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

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Xpert Check Package Insert

REF XPERTCHECK-CE-5

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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
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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
	Catalog number
	<i>In vitro</i> diagnostic medical device
	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
	Country of manufacture
	Contains sufficient for <n> tests
	Expiration date
	Control
	CE marking - European Conformity
	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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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

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.

Important

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





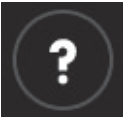




Symbol	Definition
	Information. Touch or click this icon to obtain additional information. Displays the Information Key workspace screen which has an explanation of the various module icon displays.
	Continue. This icon is located at the bottom of most screens. Touch or Click this icon to advance the 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








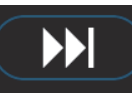
Symbol	Definition
	<p>Select none of the modules for check. Deselects all modules for checking. If you only want to check a few modules, you may deselect ALL of them, and then reselect only the ones you wish to check.</p>
	<p>Select all of the modules for checking. The default setting for the system.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

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

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](#)).

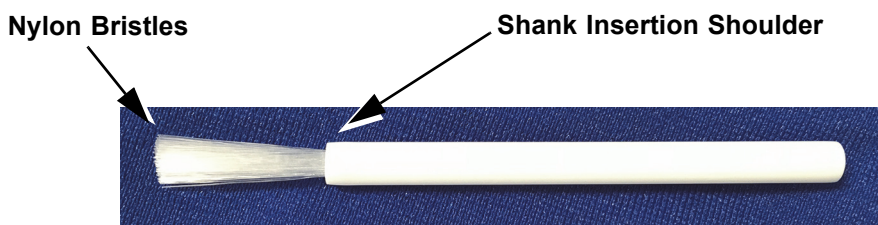


Figure 2-1. Lens Cleaning Brush (300-8330)

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.

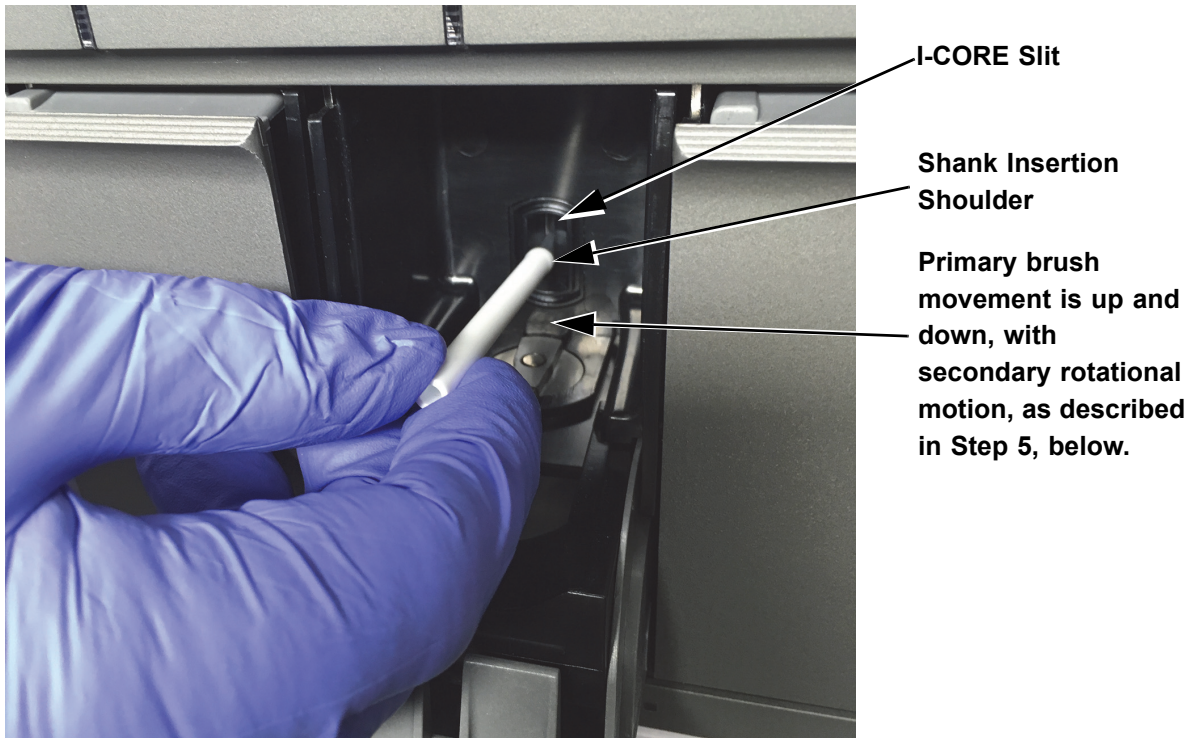


Figure 2-2. Inserting the Cleaning Brush into the I-CORE Slit

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

Note

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

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.

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](#).

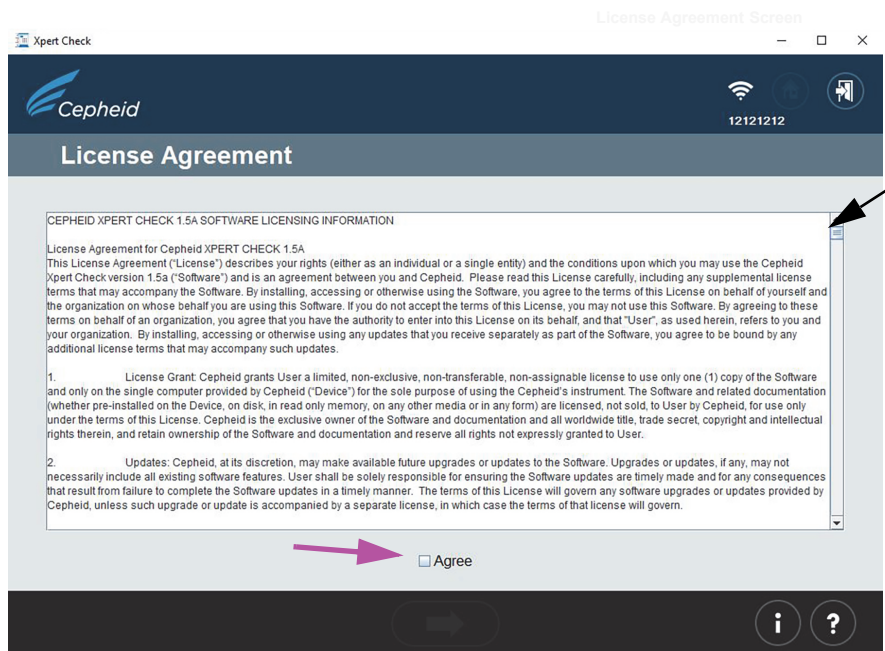
Note

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

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.



Scroll down to read the entire document.

Note: A copy of the License Agreement is located on CD1.

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.

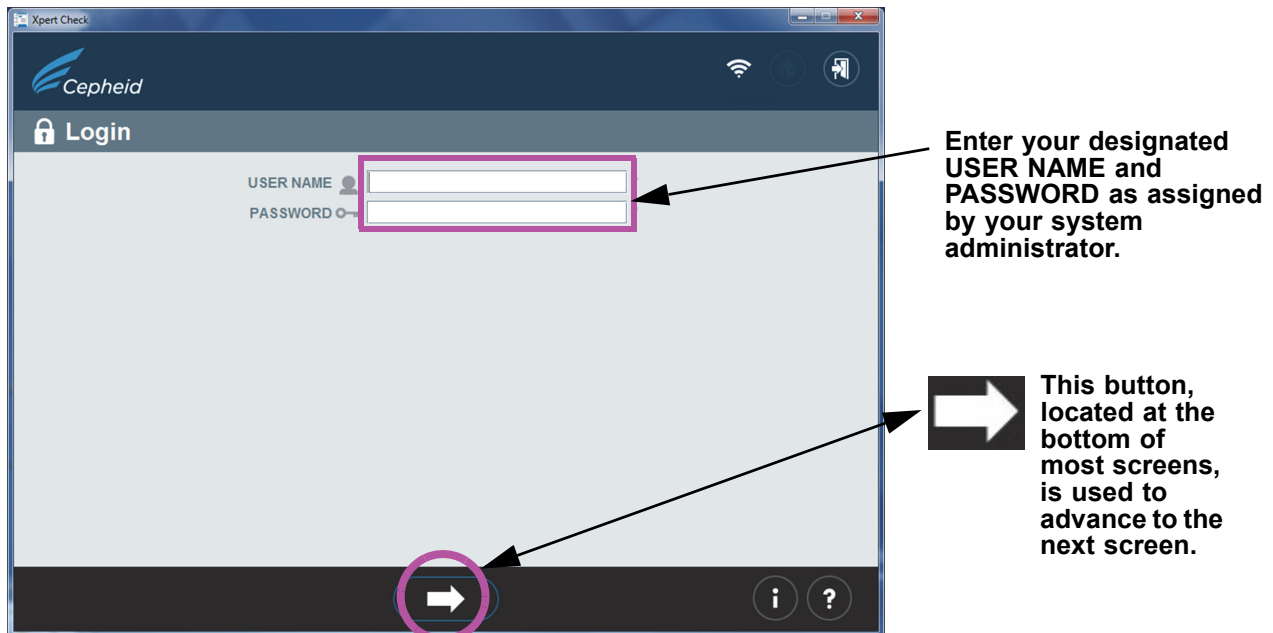


Figure 2-4. Xpert Check Login Screen

In case of a login error, the following screen will appear. See [Figure 2-5](#).

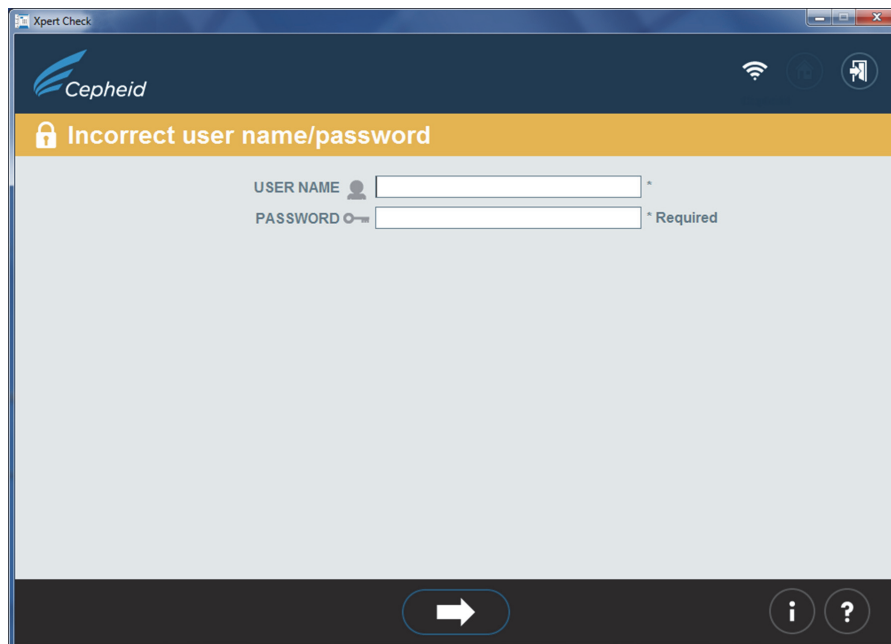


Figure 2-5. Login Error Screen

Procedure

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.

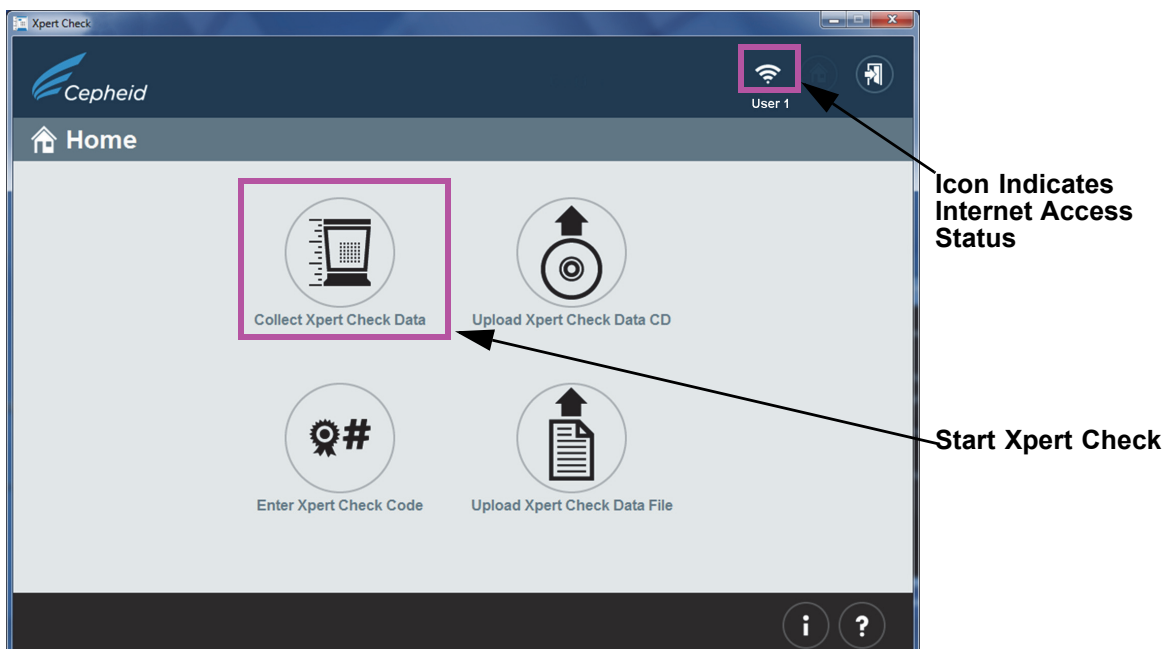


Figure 2-6. Home Screen

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.

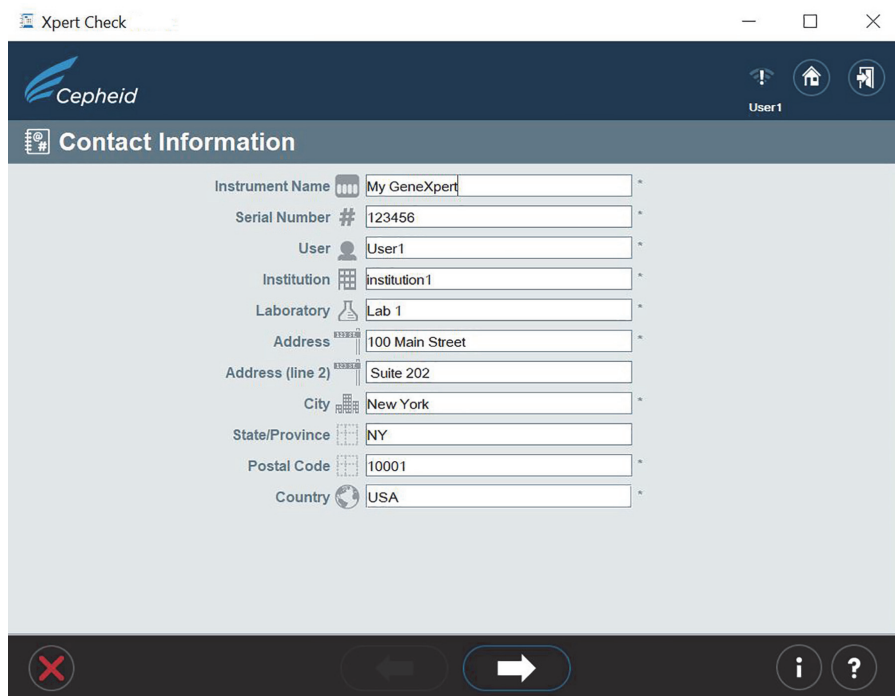
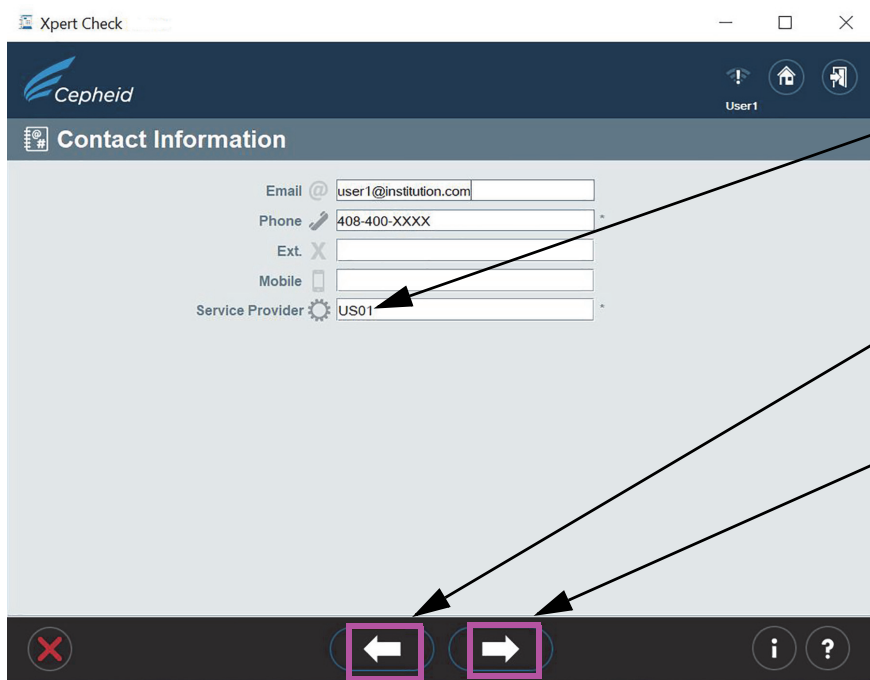


Figure 2-7. Contact Information Screen - Page 1



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.)

- 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.

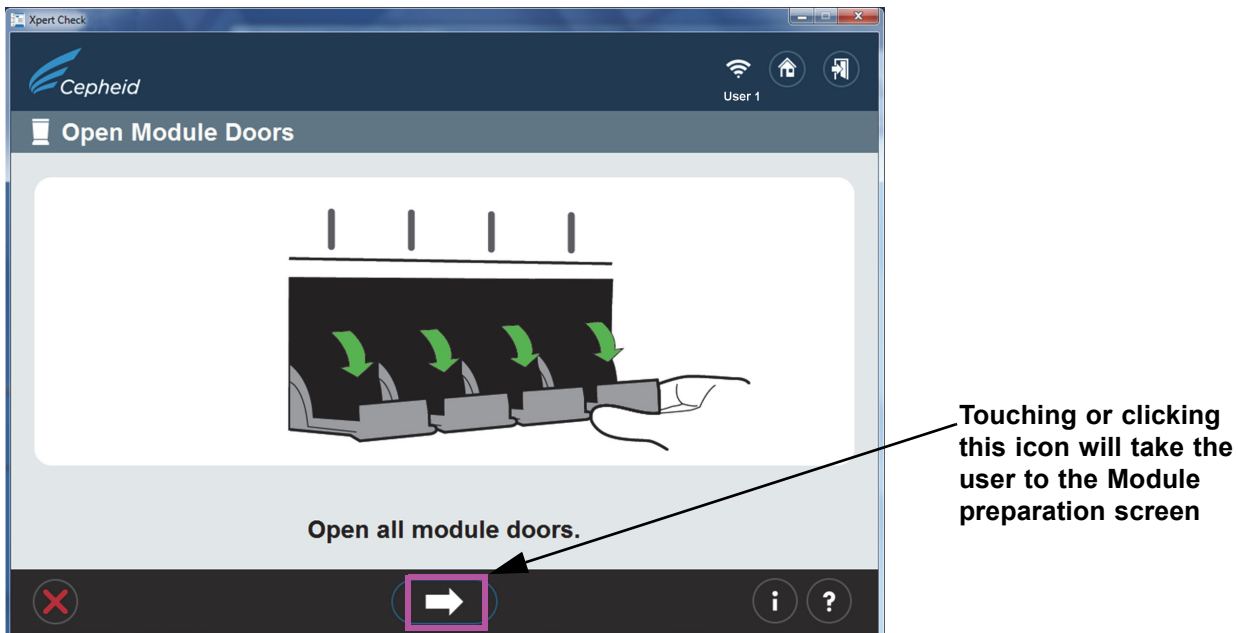


Figure 2-9. Open Module Doors Screen

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.

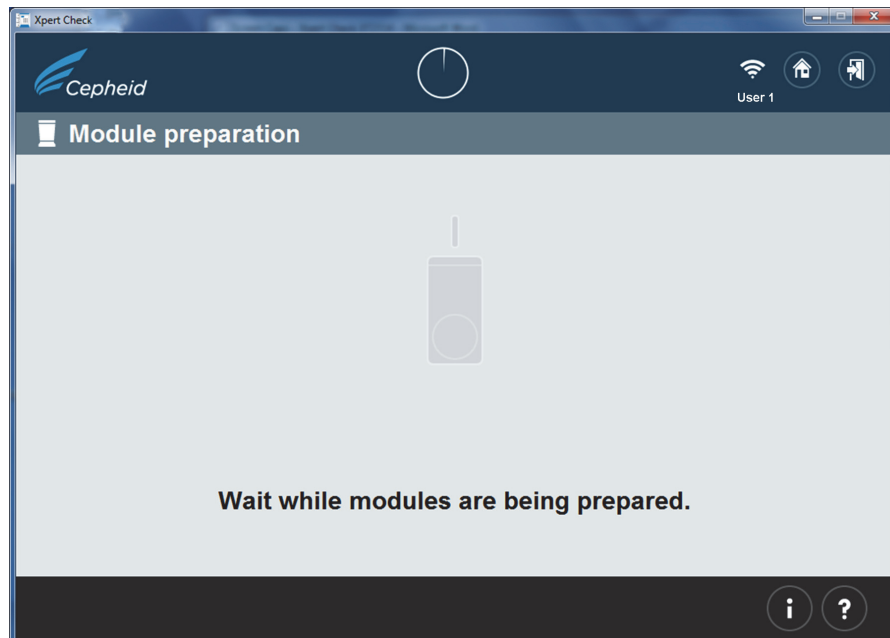


Figure 2-10. Module preparation Screen

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.

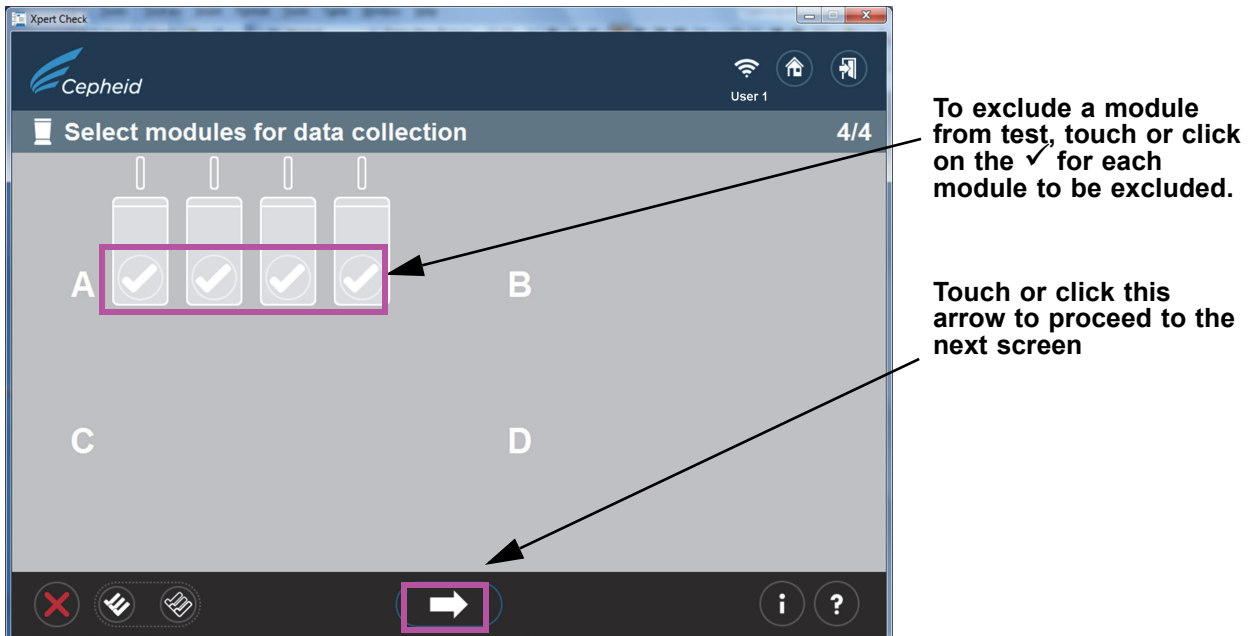
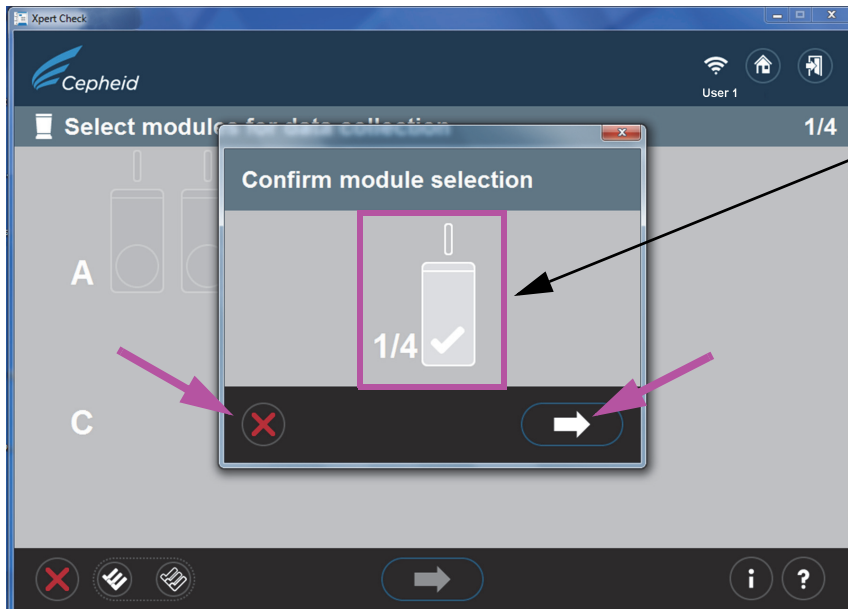


Figure 2-11. Select modules for data collection Screen

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](#).



Module selection is shown here. In this example, one module is selected for checking.

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.

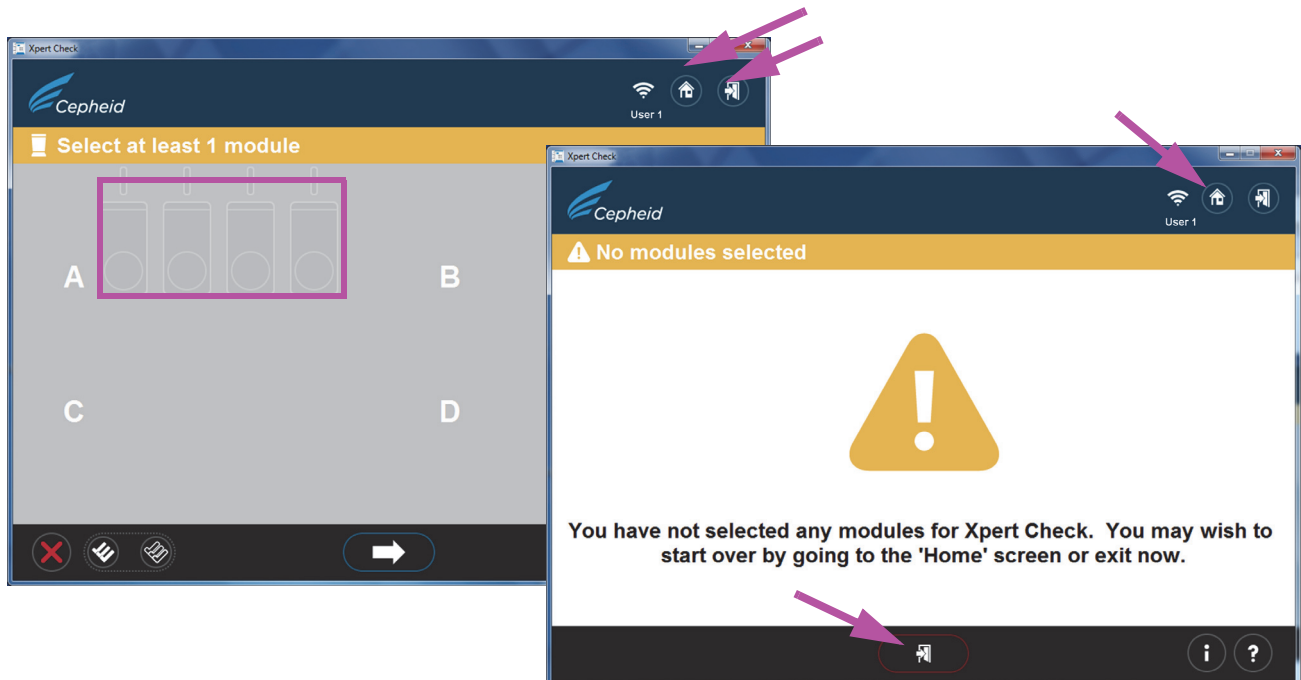


Figure 2-13. Error Screen Examples

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.

Scanning the cartridge barcode

Note: To avoid inserting a wrong cartridge into a module, do not set the cartridge aside after it has been scanned. In one operation, scan the cartridge barcode, vent the cartridge and insert it into the next available (lighted) module.

SKIP button: Touch or click this icon to skip the cartridge just scanned.

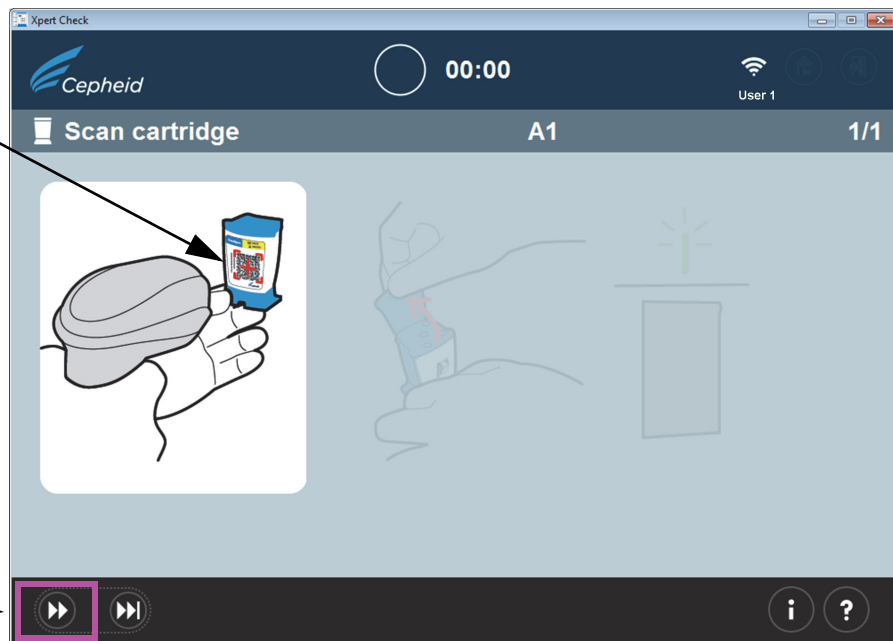


Figure 2-14. Scanning the Cartridge Barcode Screen

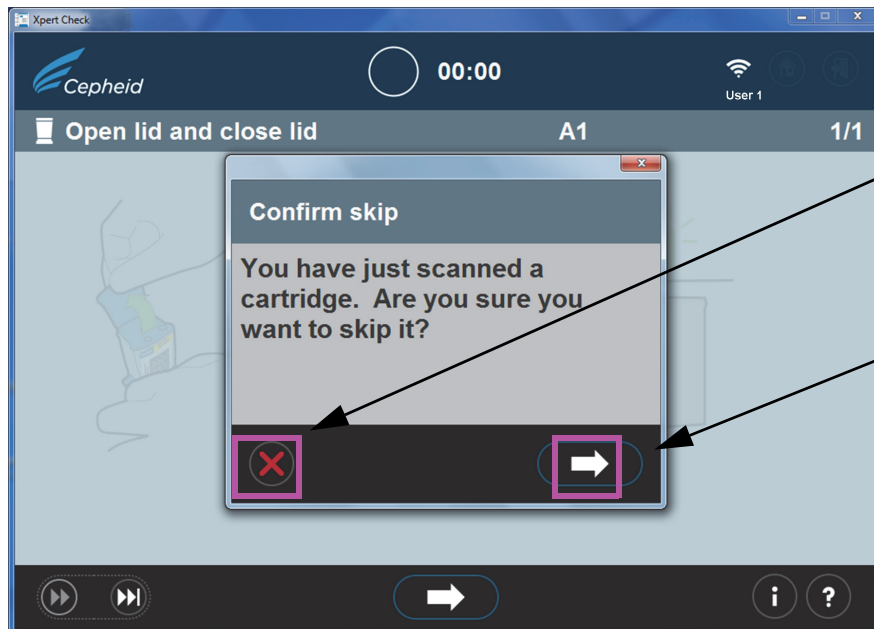
- A. After scanning the barcode of the cartridge, ensure you open (vent) the cartridge lid and then close it for each cartridge as directed by the software in [Step B](#) through [Step E](#) below.

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.

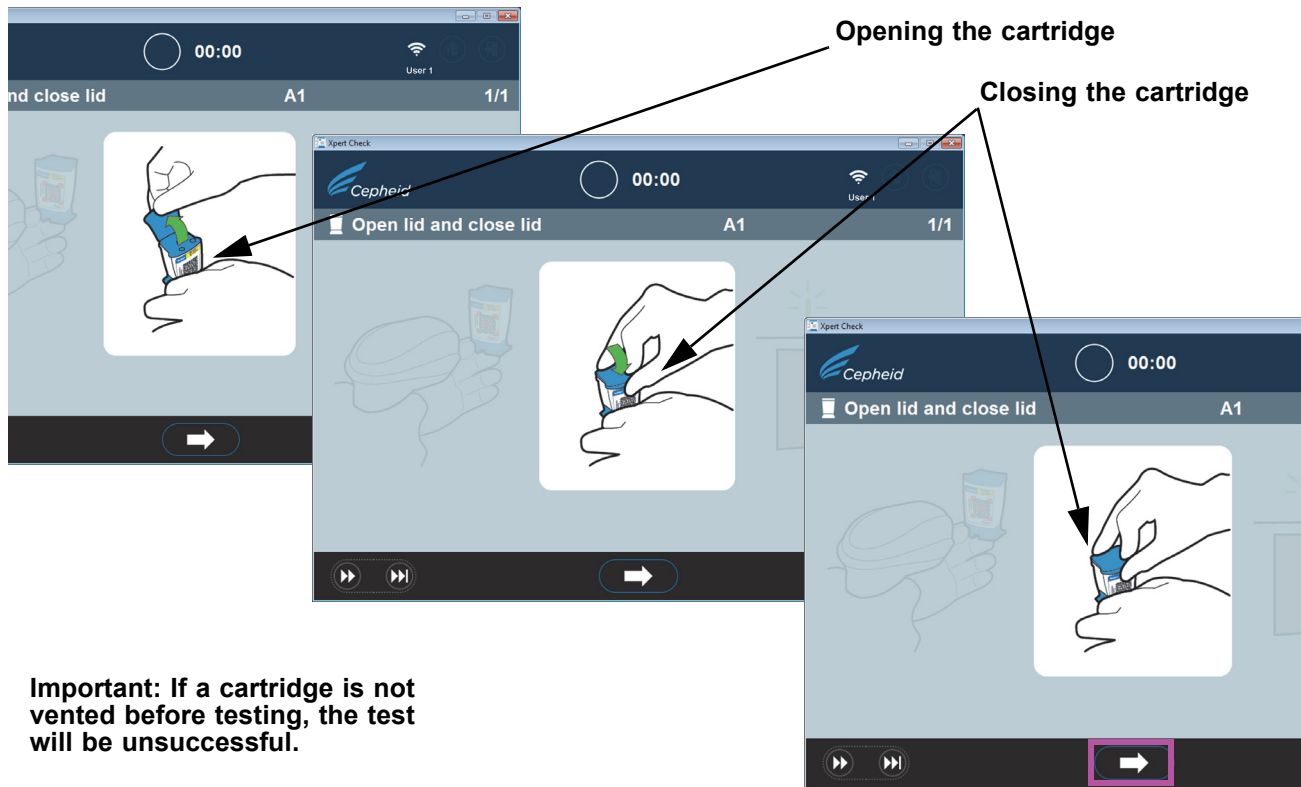


Touch or click the **X** icon to “undo” the **SKIP** selection and proceed with opening, venting and loading the cartridge into a module.

Touch or click the arrow to confirm you want to skip the cartridge just scanned.

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.



Important: If a cartridge is not vented before testing, the test will be unsuccessful.

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.

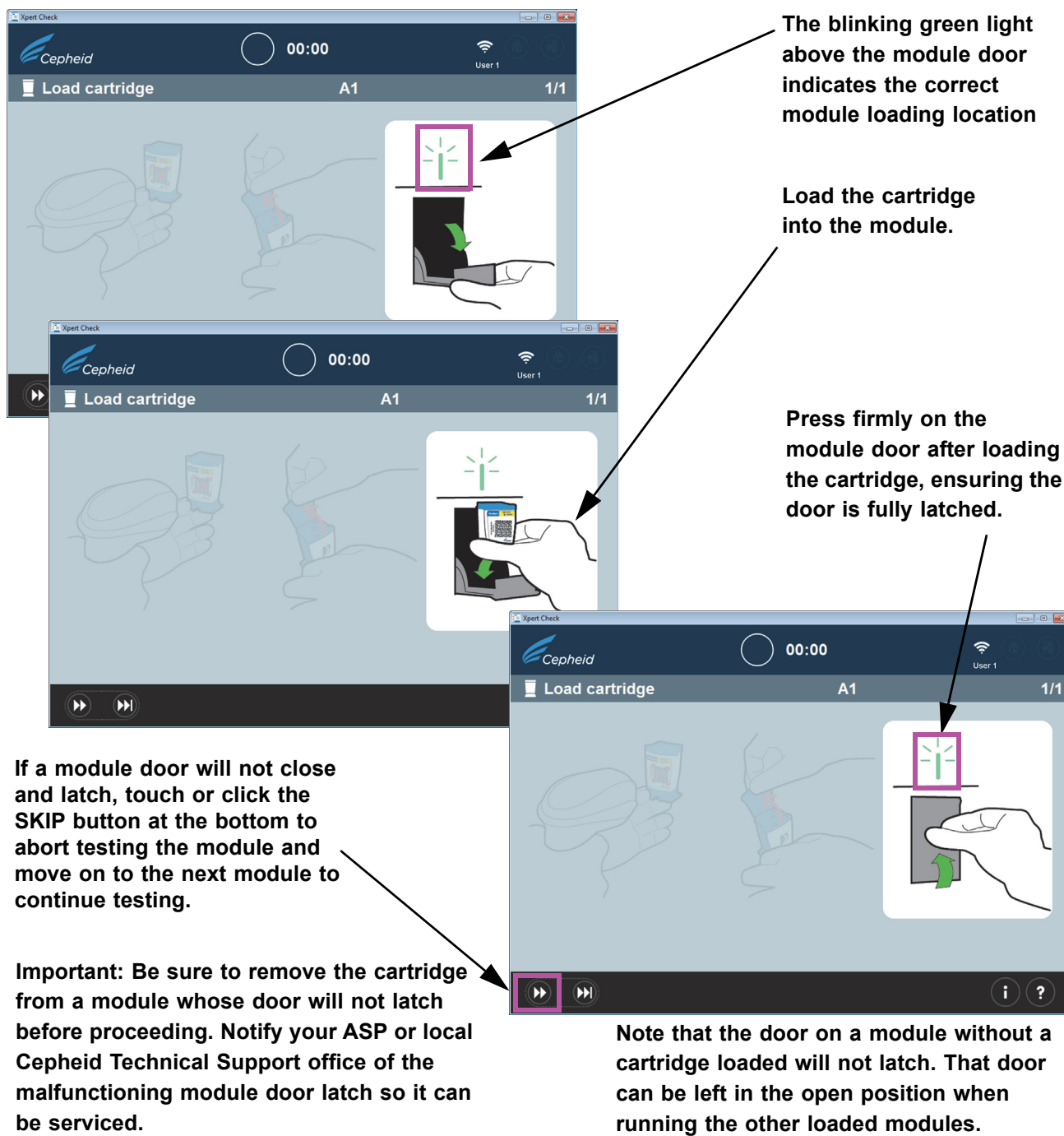


Figure 2-17. Loading the Cartridge into the Module

- 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.

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.

Important

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.

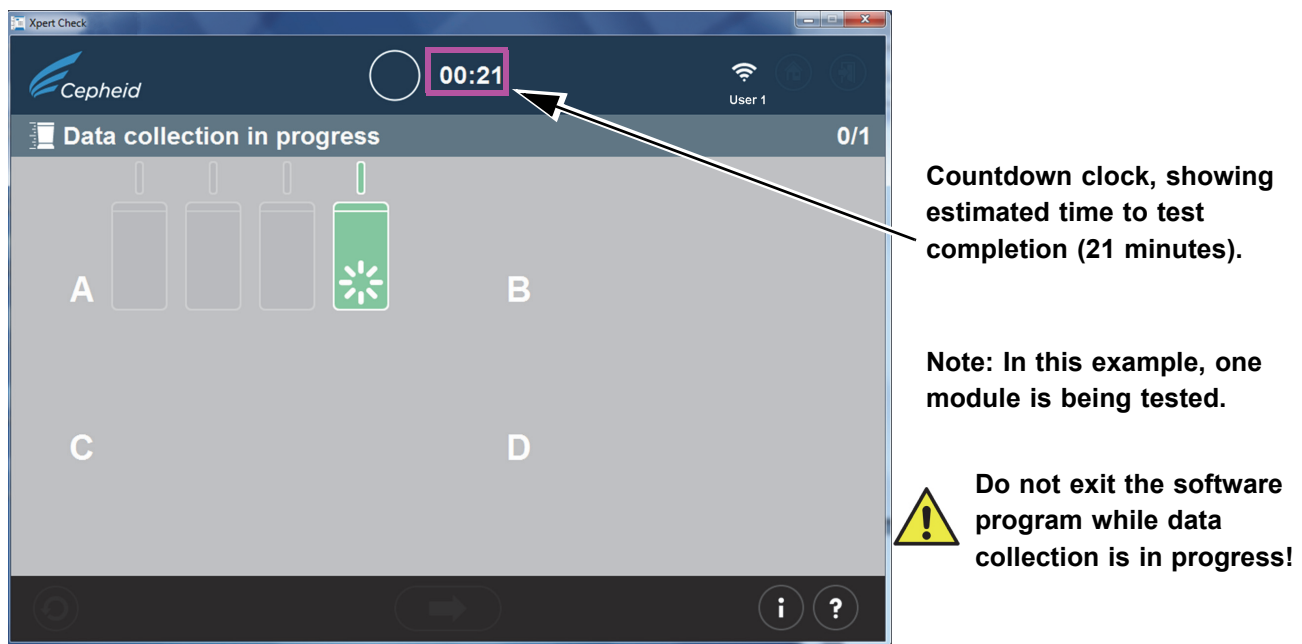


Figure 2-18. Data Collection Screen

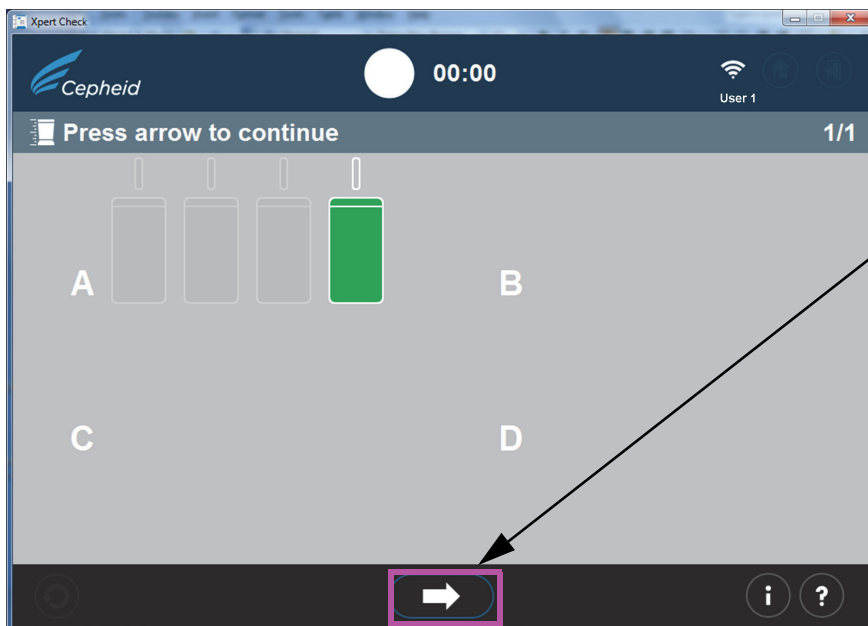
Important

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.



Touch or click to continue to the next screen.

Note: In this example, one module is being tested.

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.

Module test unsuccessful. Test must be rerun using either the same or a new cartridge, as instructed by the on-screen display.

Continue button. Touch or click to proceed without retesting. See Figure 2-21.

Retry Icon: Touch or click to retest the module.

Note: In this example, one module is tested.

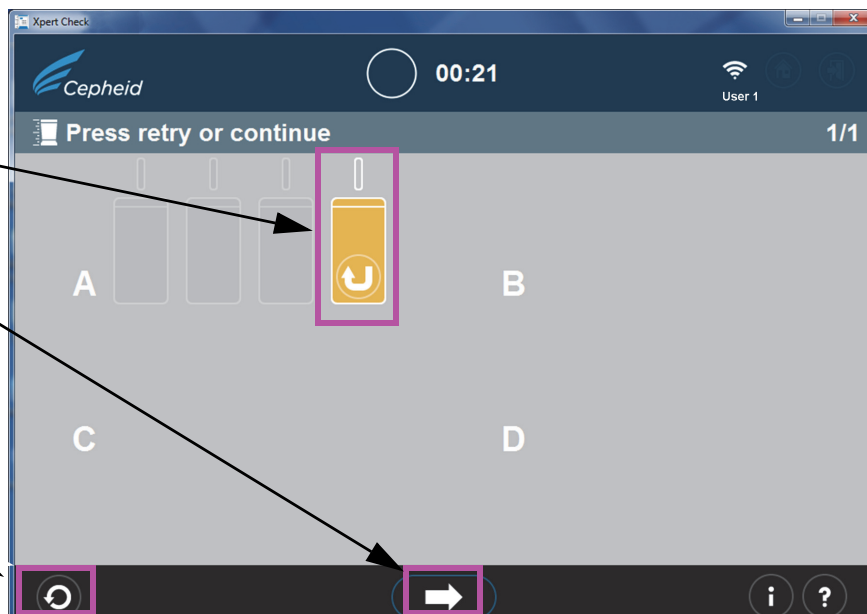


Figure 2-20. Test Completion Screen - Unsuccessful Module Checking Example

- 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.

To return to the Press retry or continue screen to retest the flagged module, touch or click the X icon.

To continue without retesting the flagged module, touch or click the right arrow at the bottom of the Confirm continue screen.

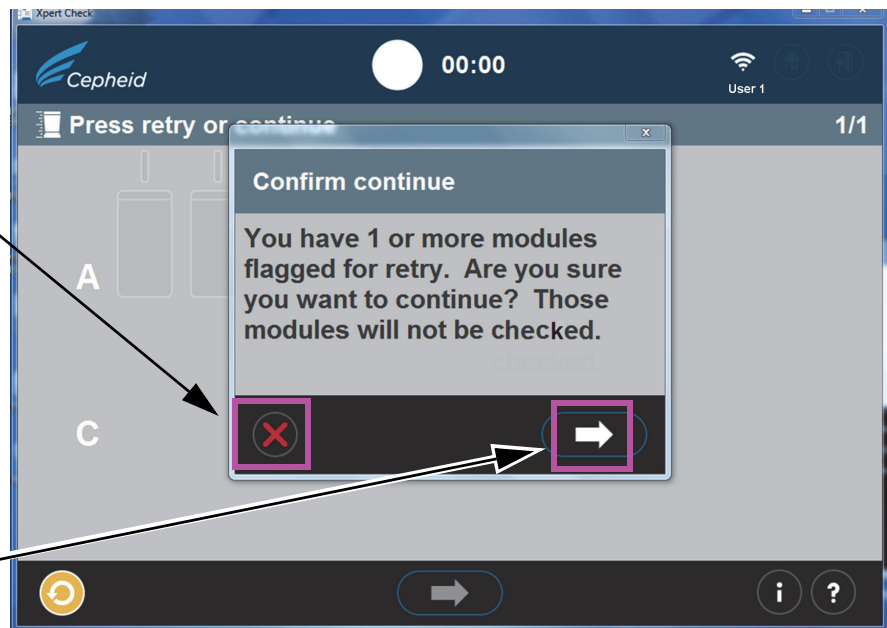


Figure 2-21. Confirm Continue Screen Overlay

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.

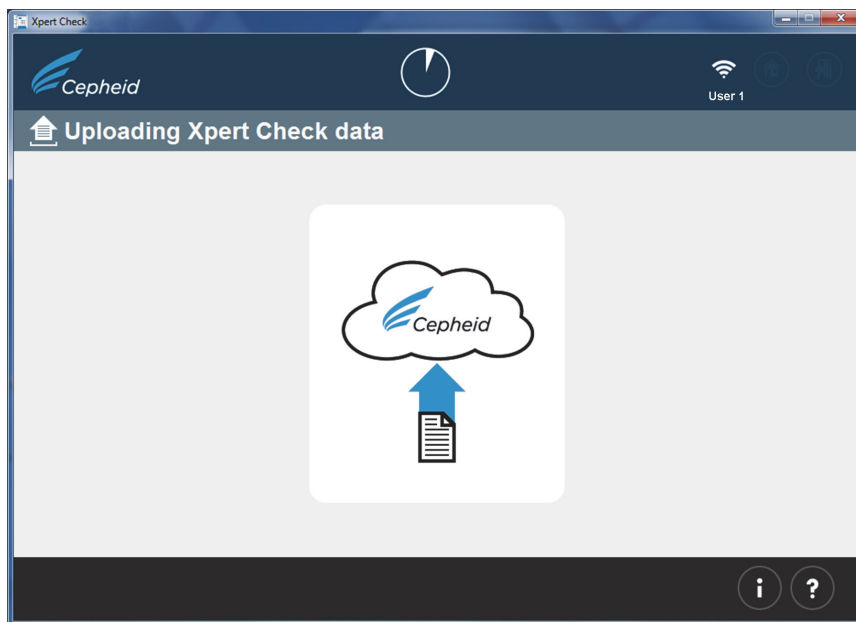


Figure 2-22. Uploading Xpert Check Data Screen

Touch or click this icon to move to the Write Xpert Check Data to CD screen. See Figure 2-31.

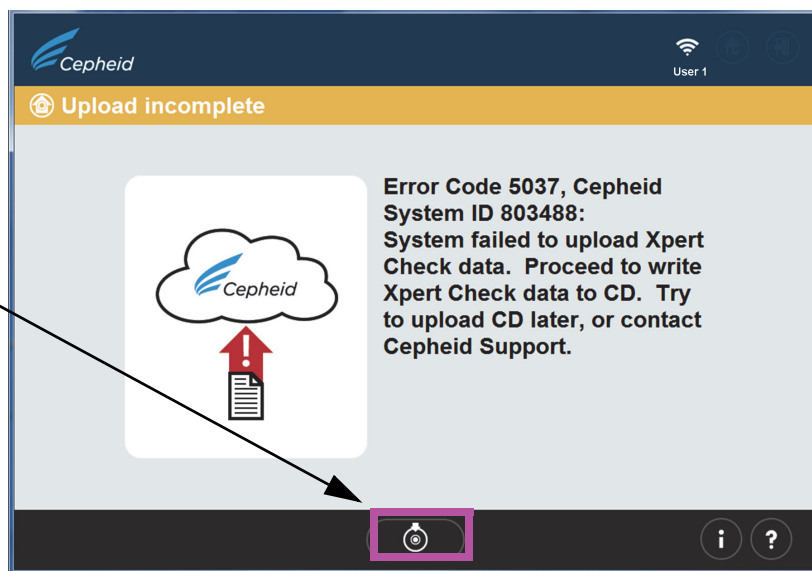


Figure 2-23. Upload incomplete Error Screen

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.

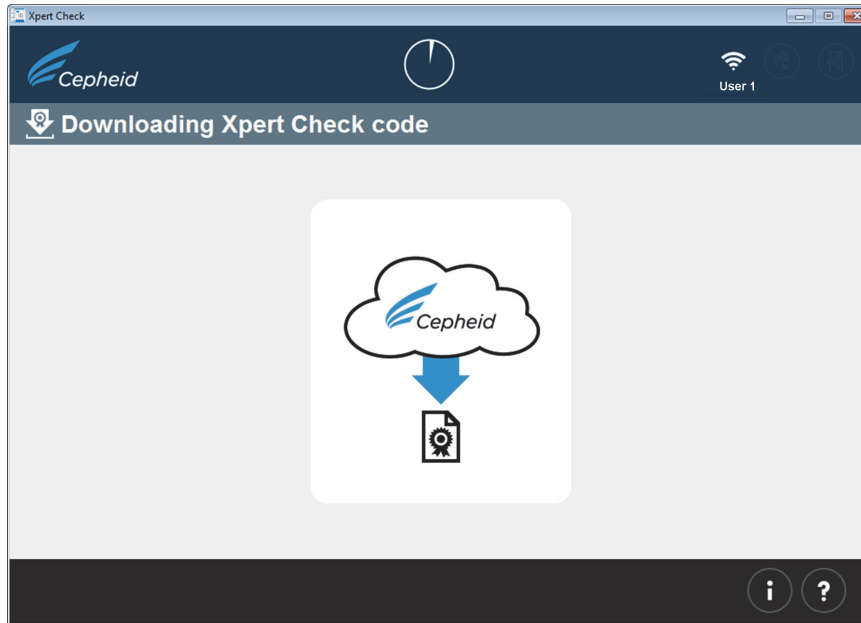


Figure 2-24. Downloading Xpert Check code Screen

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.

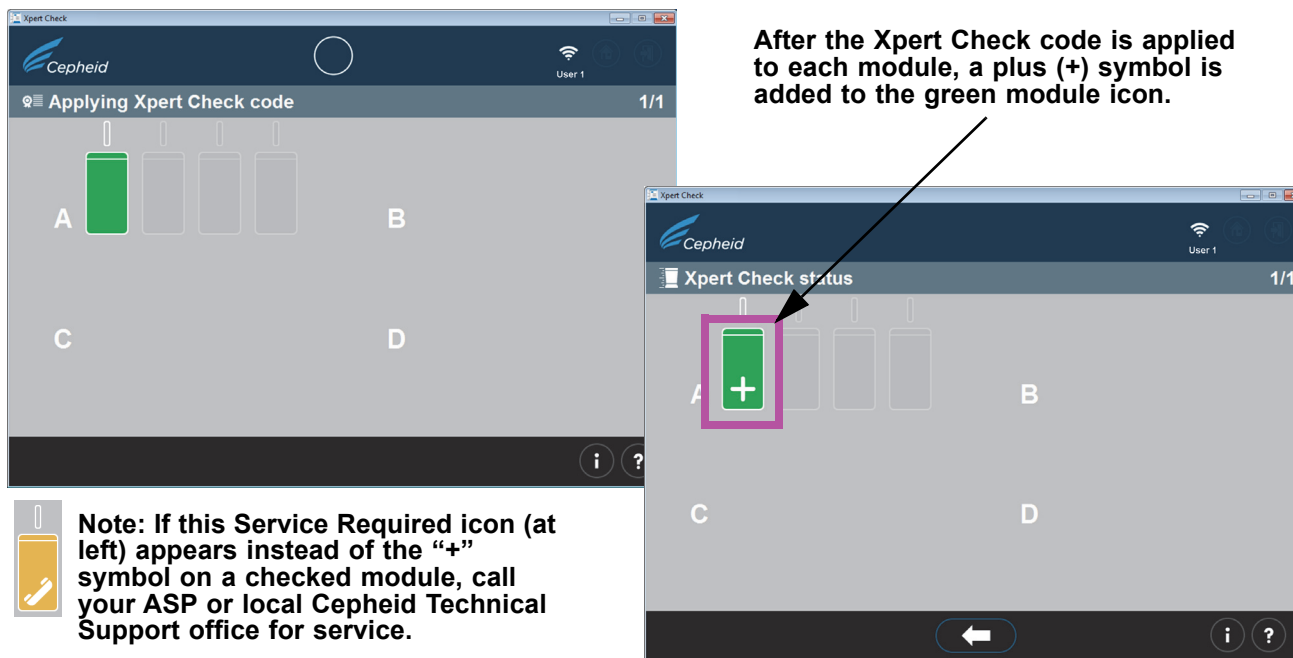


Figure 2-25. Applying Xpert Check code Screen

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.

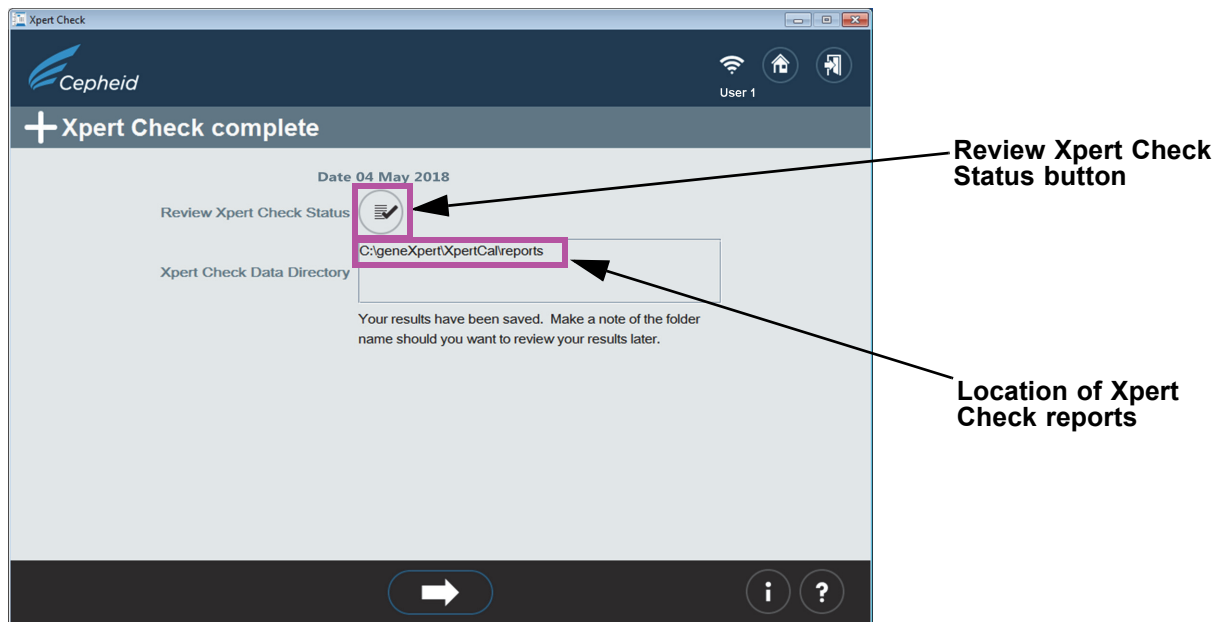


Figure 2-26. Xpert Check complete Screen

- 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](#).

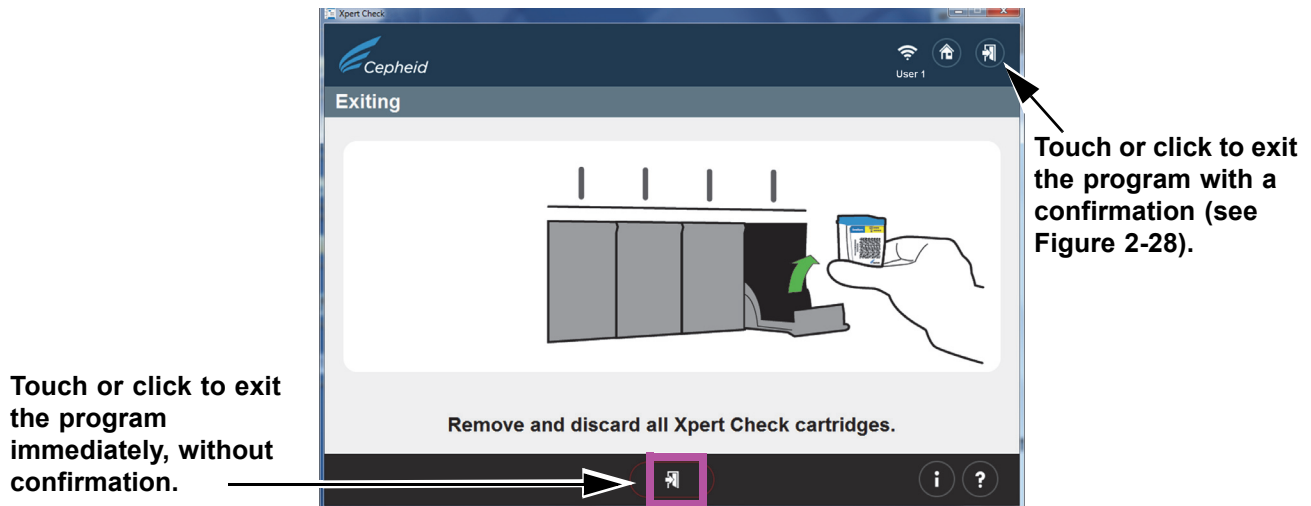
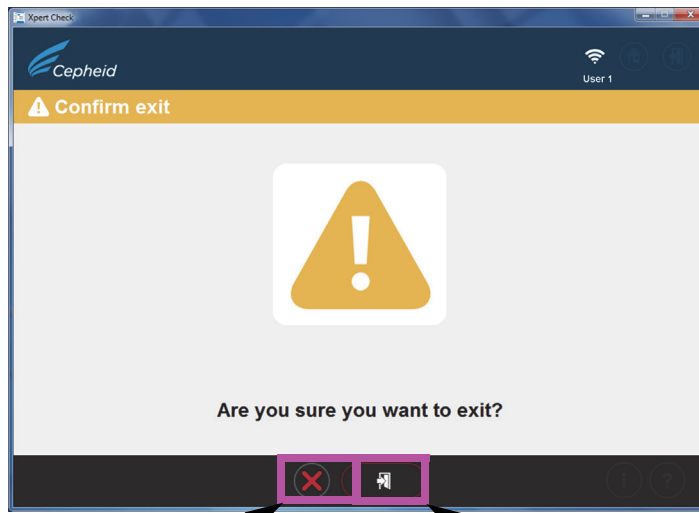


Figure 2-27. Exit the Program

- 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.



Touch or click to abort the exit command

Touch or click to confirm and exit the program

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.

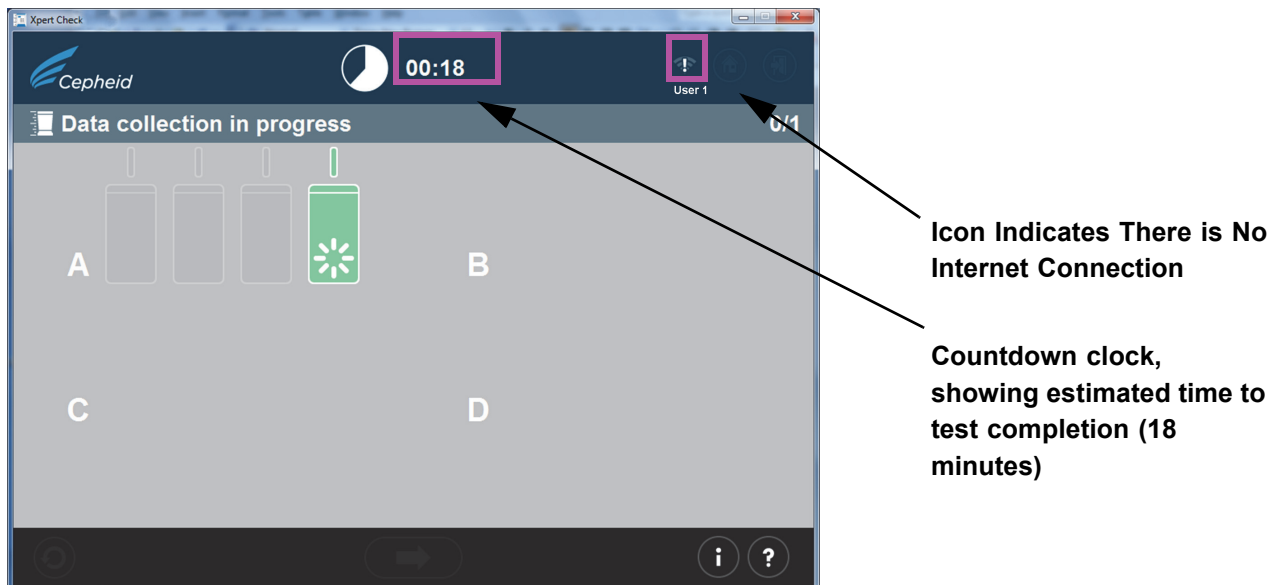


Figure 2-29. Data collection in progress Screen

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.

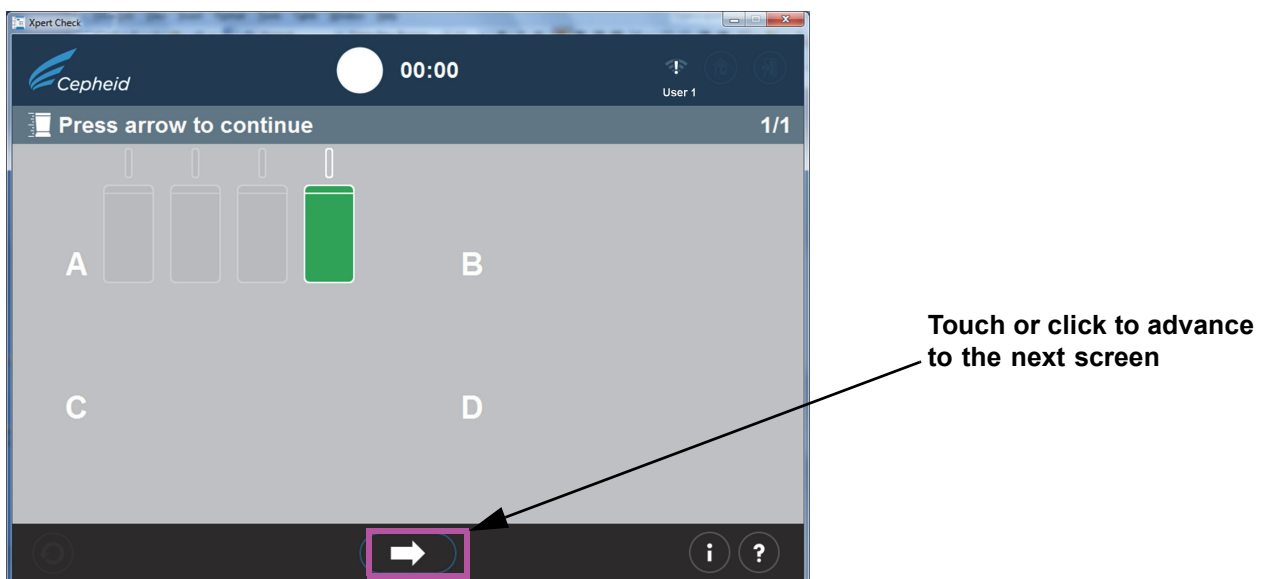


Figure 2-30. Test Completion screen - Successful

- 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.

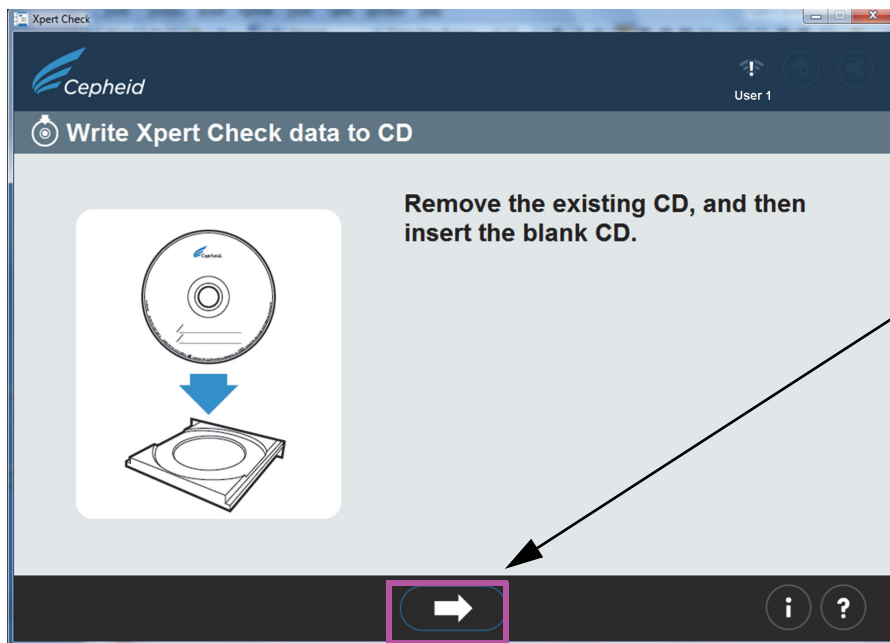
Note In the following step, use care in inserting the blank CD into the DVD drive. Be sure the CD is fully seated in the tray before closing the drive door.

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.

- 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.



Pause 10 seconds after CD insertion and then touch or click to continue to the next screen.

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

- 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.

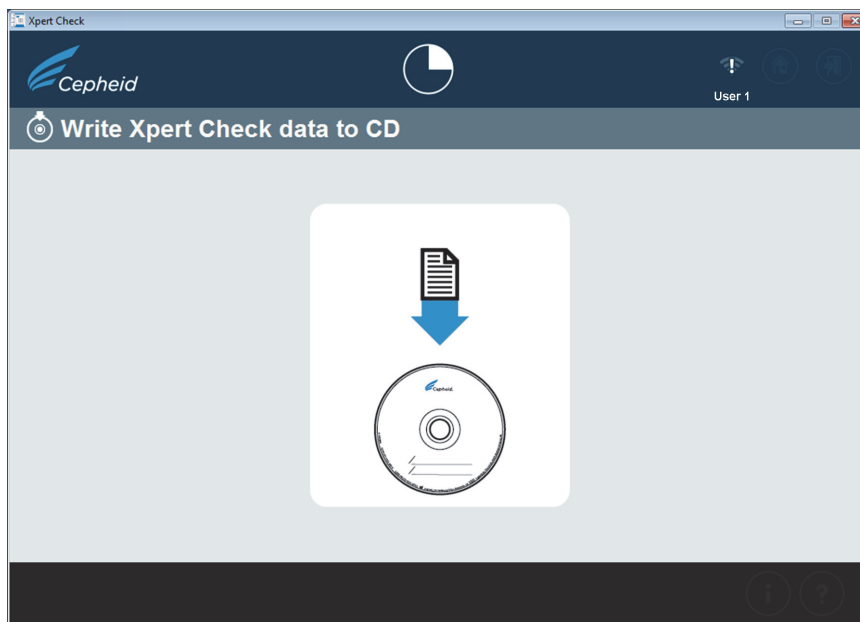


Figure 2-32. Write Xpert Check data to CD screen - Step 2

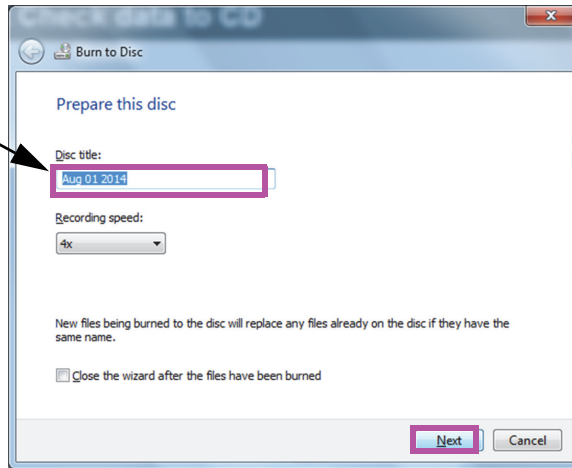
6. The CD Writing Wizard or Burn to Disc screen (Figure 2-34) will then appear as an overlay of the screen shown above, in Figure 2-32.

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

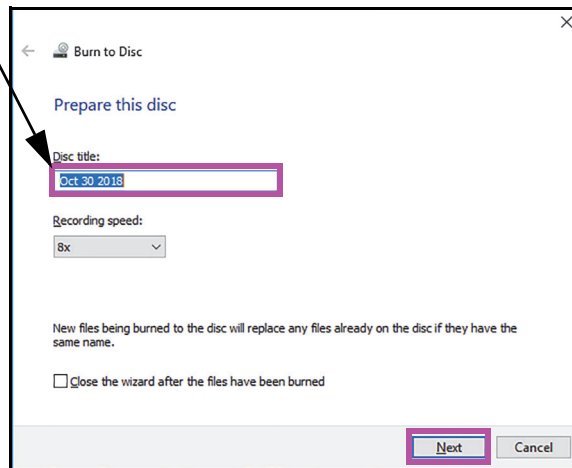
- Windows[®] 7 users: Follow the screens on the top of the figure.
- Windows[®] 10 users: Follow the screens at the bottom of the figure.

- 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.

Type in your facility name
for the CD name/Disc title



Opening Screen - Windows 7



Opening Screen - Windows 10

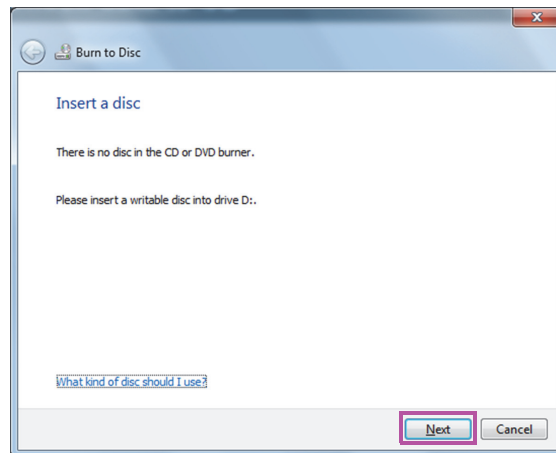
Figure 2-33. CD Writing Program - Opening Screen

- 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.

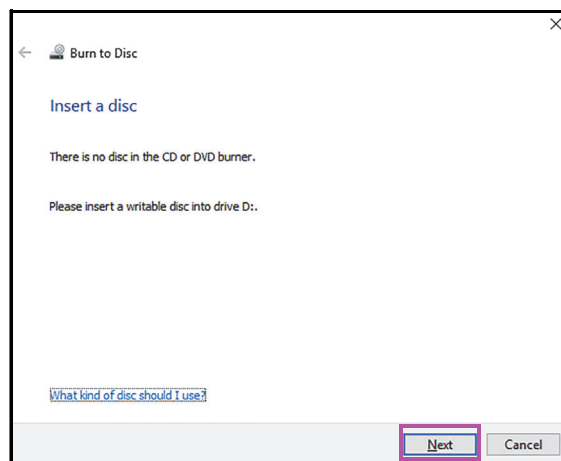
A disc that has data on it is not considered to be a writable disc and will result in an error screen, as shown in [Figure 2-39](#).

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.



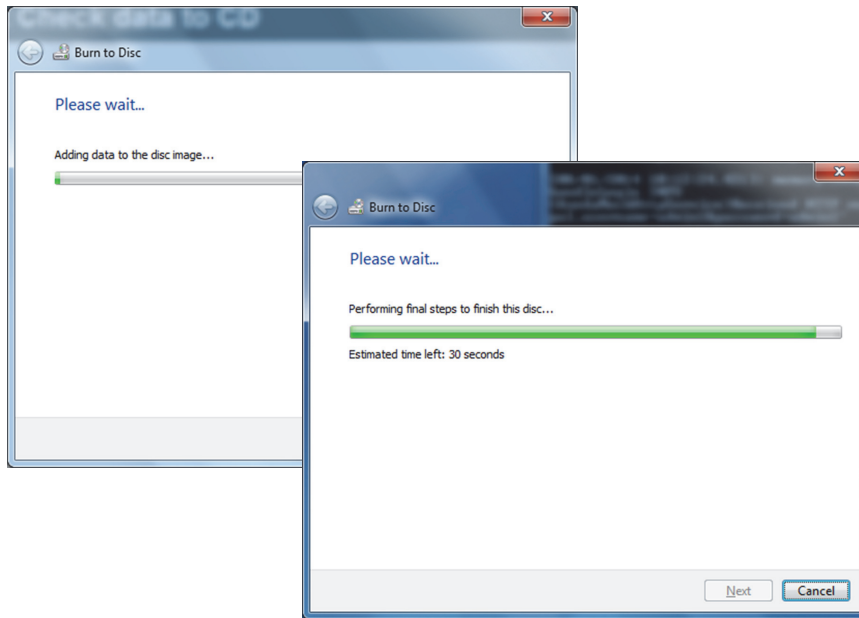
Insert a Disc Screen - Windows 7



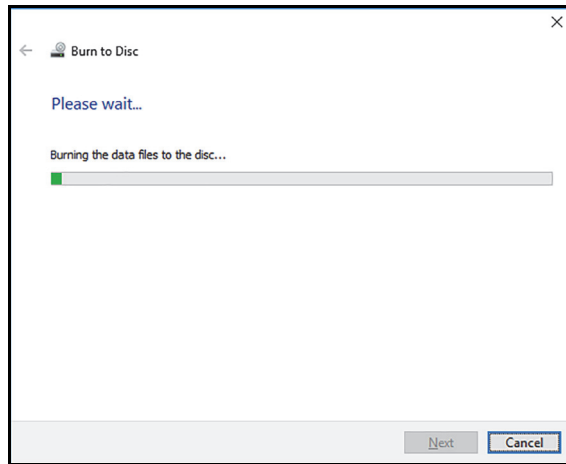
Insert a Disc Screen - Windows 10

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](#).



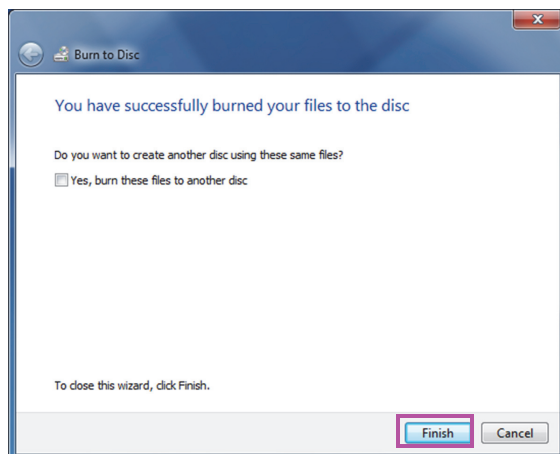
File Burning Progress Screens - Windows 7



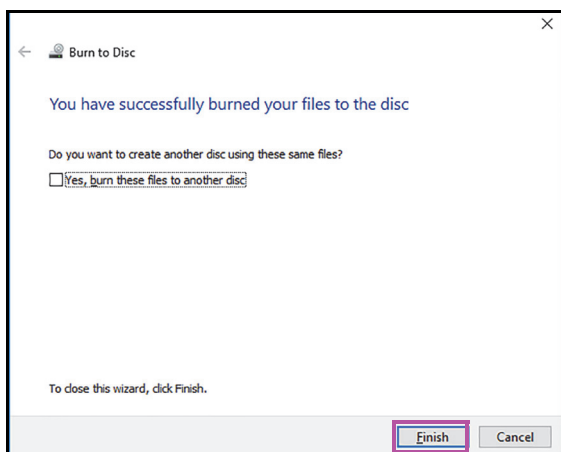
File Burning Progress Screen - Windows 10

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.

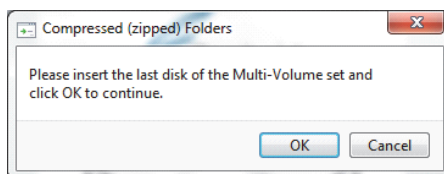


Figure 2-37. Final Screen from Windows 7 After CD Writing has Completed

- 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](#).

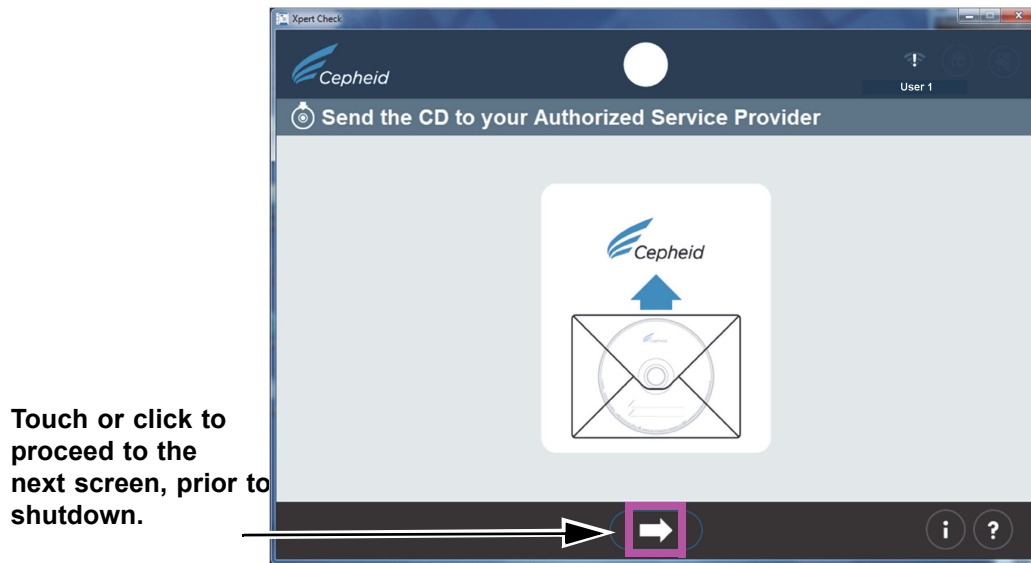
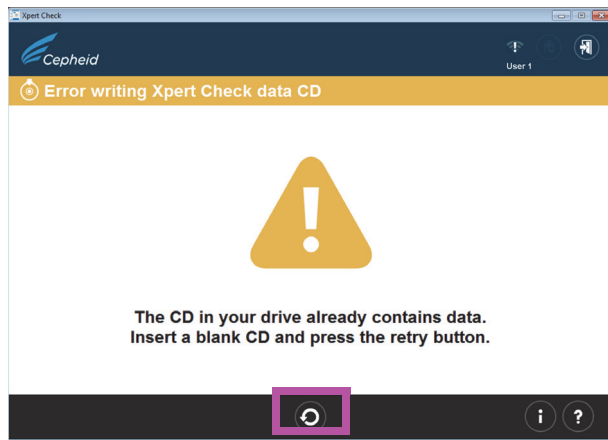


Figure 2-38. Send the CD to your Authorized Service Provider Screen - Step 3

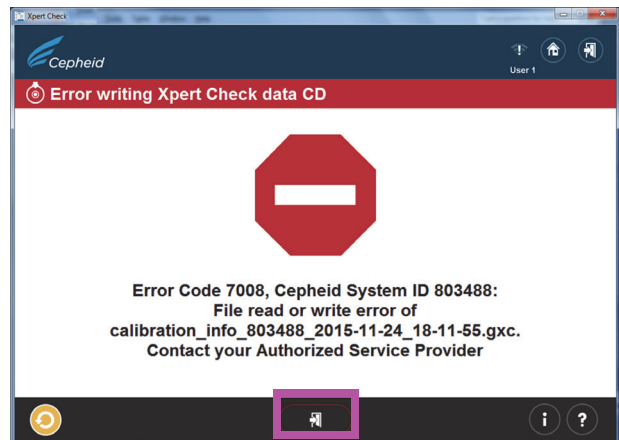
8. If a problem has occurred anytime during the CD writing process, an error code screen may appear. (See Figure 2-39).
 - If a CD you have inserted already contains data as shown in the error screen below at the left, remove the CD and insert a blank CD, and then touch or click the **Retry** icon.
 - 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

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

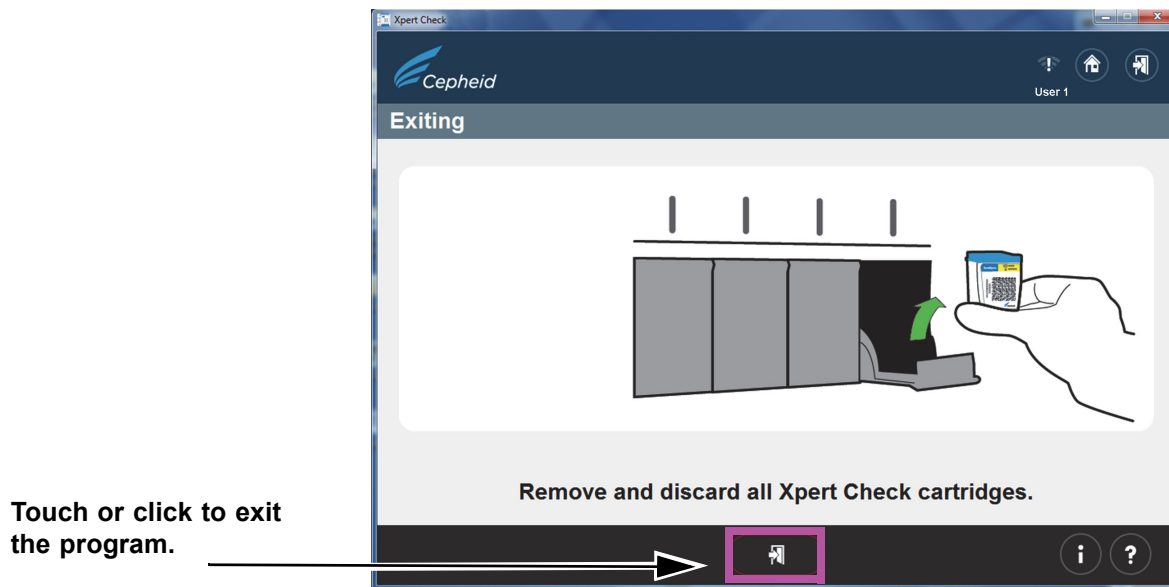


Figure 2-40. Exiting Screen

- 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.

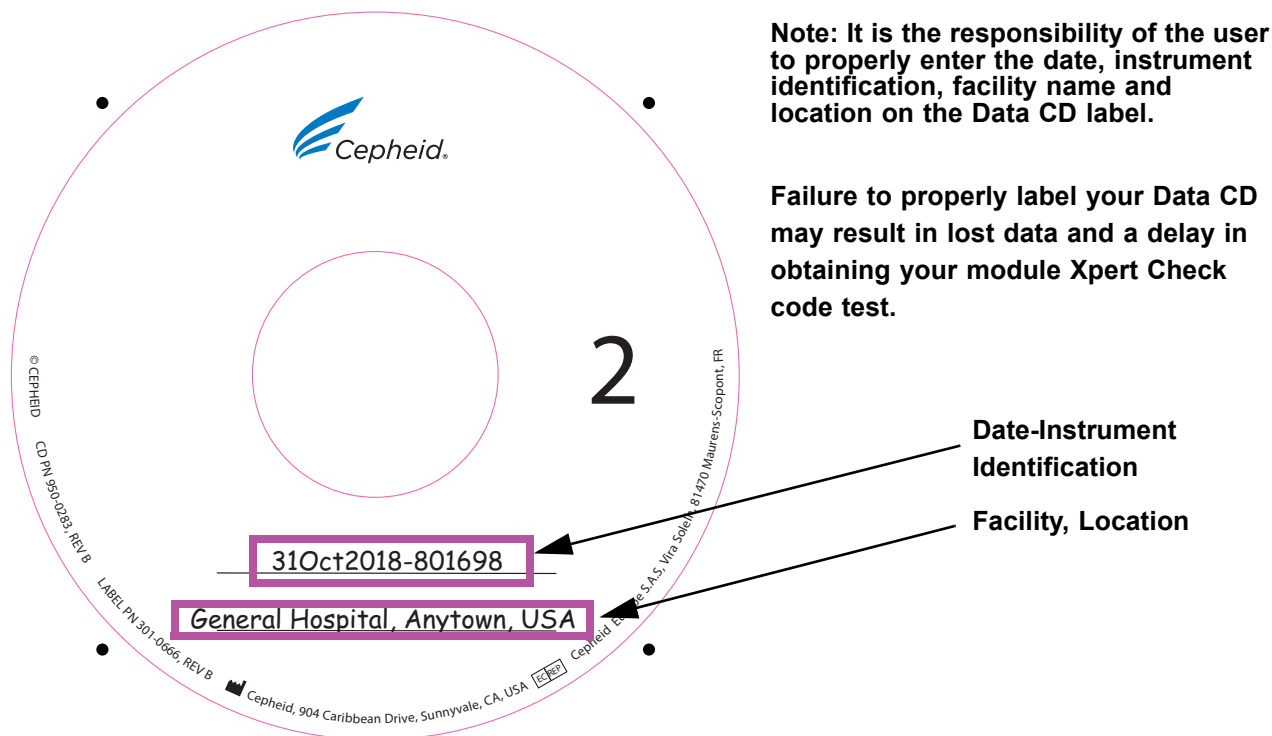


Figure 2-41. Data CD Labeling Example

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.

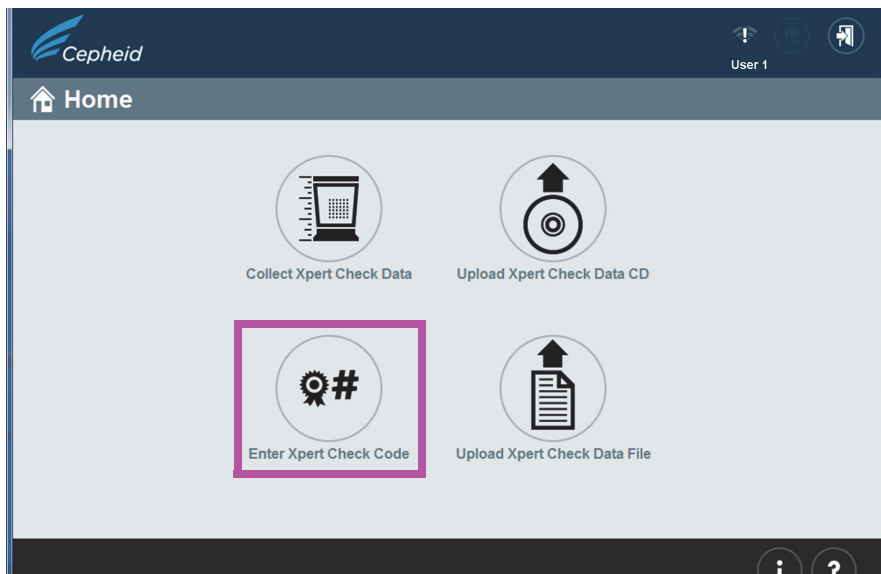


Figure 2-42. Home Screen, showing Enter Xpert Check Code Button

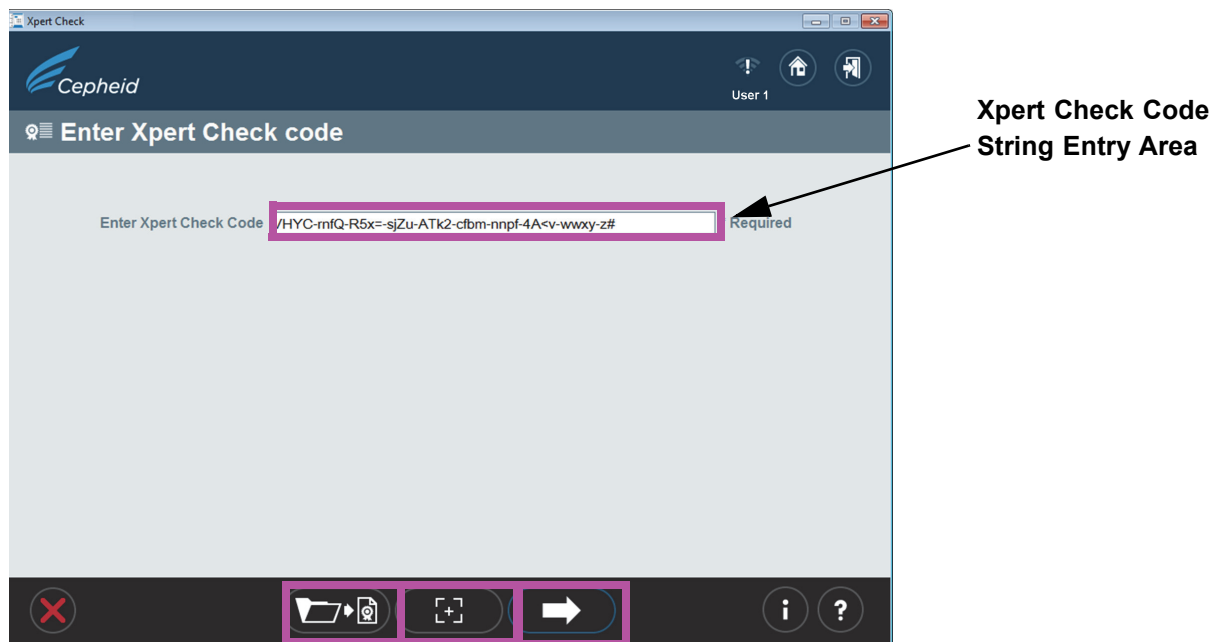


Figure 2-43. Enter Xpert Check code Screen

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.



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.

Figure 2-44. Xpert Check Code File - Example

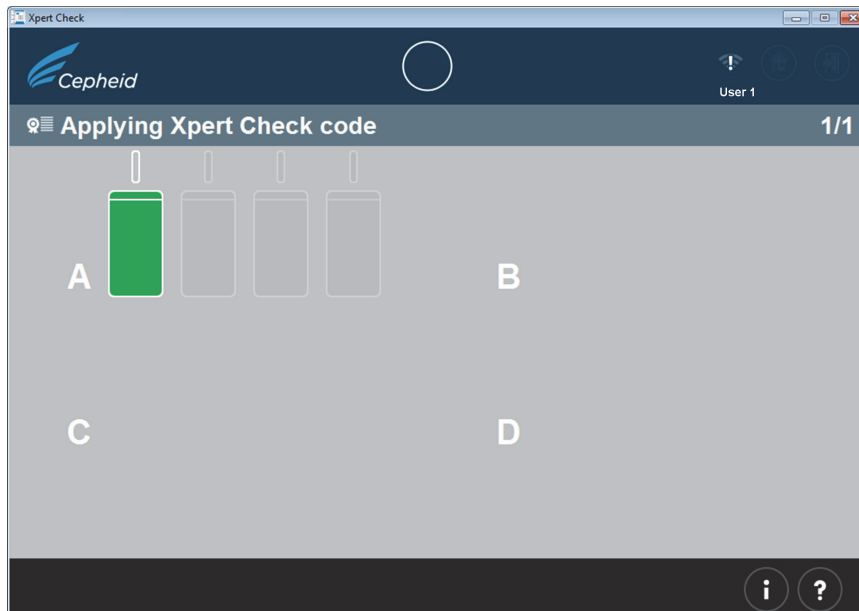


Figure 2-45. Applying Xpert Check code Screen Example

- 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.

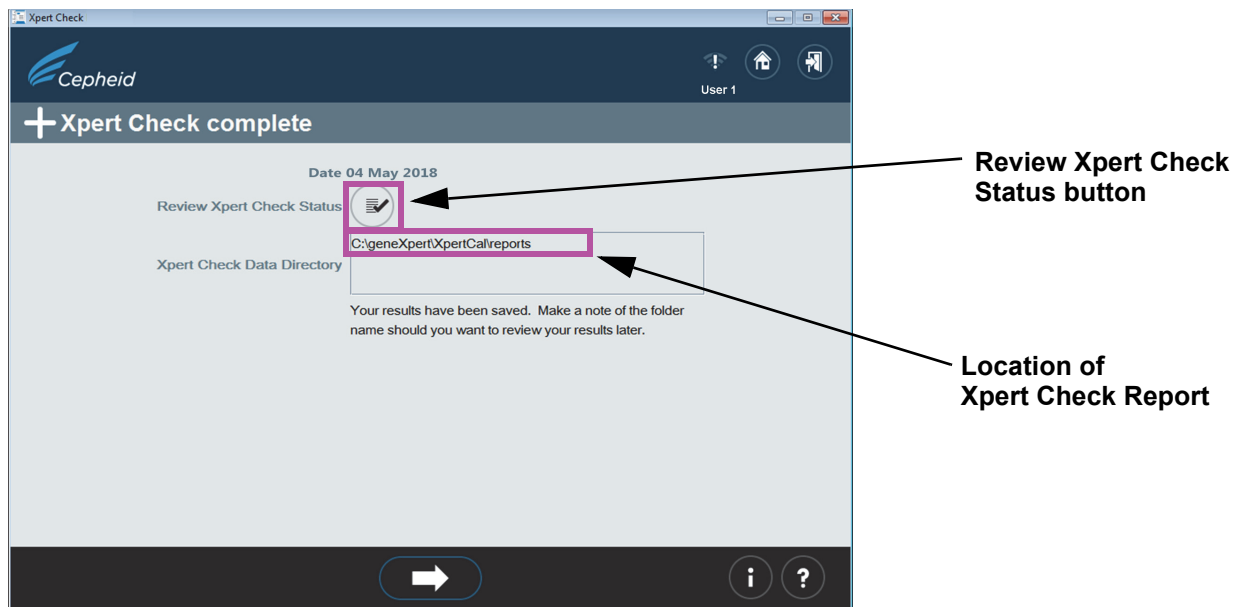


Figure 2-46. Xpert Check complete Screen

- 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.

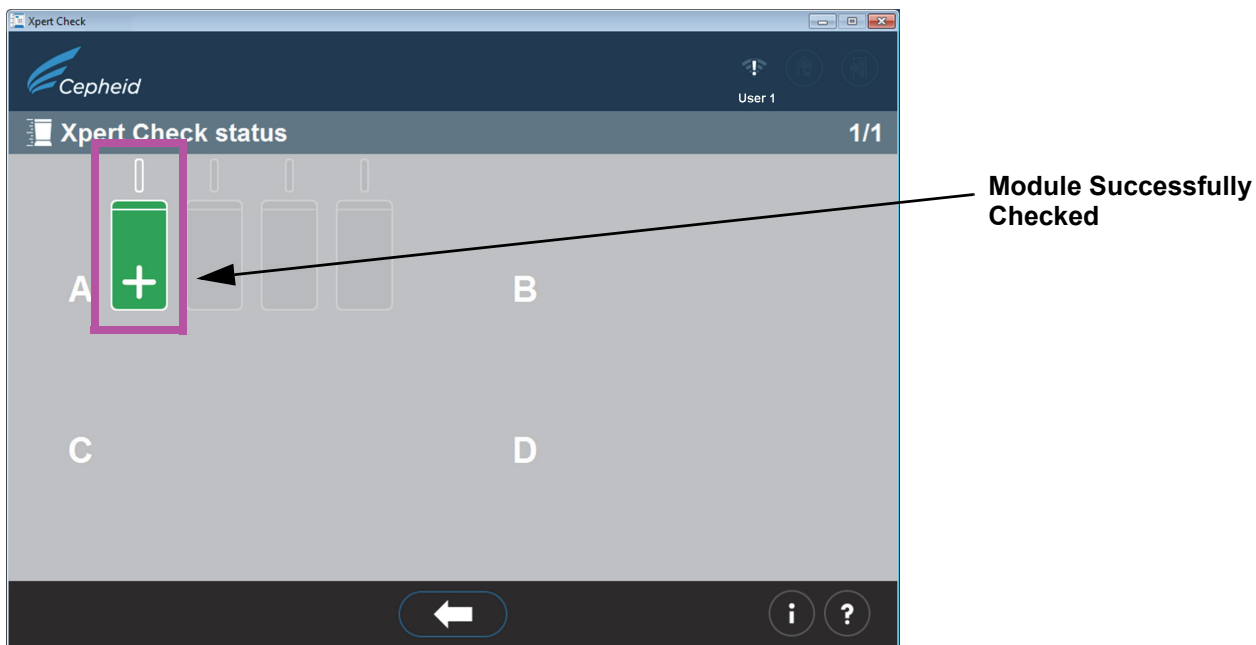


Figure 2-47. Xpert Check status Screen

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



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



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.

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

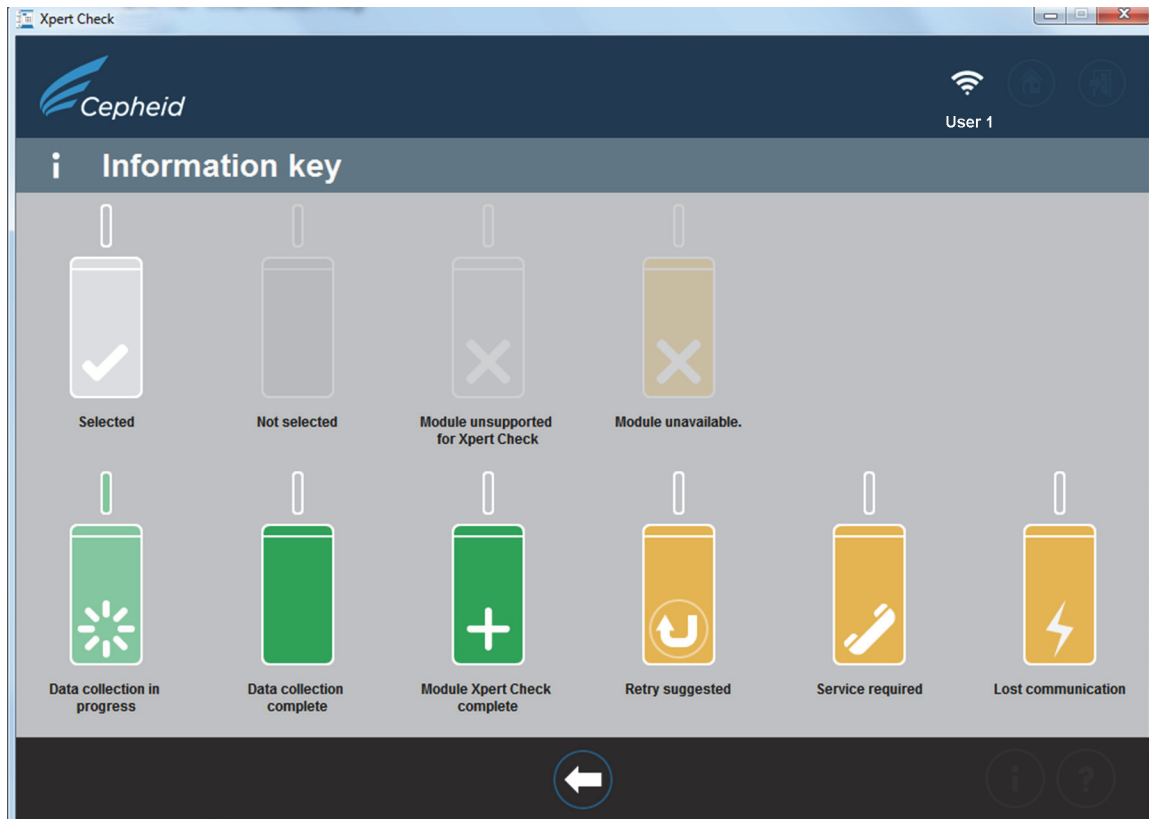


Figure 2-50. Information key Screen

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.

