

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

CERERE DE PARTICIPARE

Către: **IMSP Institutul Mamei si Copilului,**
(mun.Chișinău, str.Burebista, 93)

Stimați domni,

Ca urmare a anunțului de participare apărut în Buletinul achizițiilor publice nr. _____ din 13.06.2024, privind aplicarea procedurii pentru atribuirea contractului de achiziționare a **Reactivi și consumabile de laborator, repetat (lista neacoperită de CAPCS)**, 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, neavând obiecții la documentația de atribuire.

Data completării 20.06.2024

Cu stimă

Ofertant/candidat

Gabriela-Cristina Anghel



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

1308516

Din
От

19.06.2024 13:08



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1018600004516

Denumirea

Наименование

Societatea cu Răspundere Limitată MEDIST GRUP



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI

INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ

ЗАДОЛЖЕННОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

04.07.2024 13:08



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 19.06.2024 13:08

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are același valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью (msign.gov.md)

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:

- Termenul de valabilitate a produselor livrate va constitui cel puțin 80% din termenul de valabilitate inițial, care este de minimum 3 luni de la momentul livrării acestora de la producator conform declaratiei atasate prezentei.
- În caz de solicitare, mostrele vor fi prezentate în termen de 15 zile.

Data: 20.06.2024

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

**DECLARAȚIE
privind valabilitatea ofertei**

Către **IMSP Institutul Mamei si Copilului,**
(mun. Chișinău, str.Burebista 93)

Stimați domni,

Ne angajăm să menținem oferta valabilă, privind achiziționarea **Reactivi și consumabile de laborator, repetat (lista neacoperită de CAPCS)**, prin procedura de achiziție – **Licitație deschisă**, pentru o durată de **60 zile** (șasezeci zile) respectiv până la 30 August 2024 și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 20.06.2024

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

Entitatea: MEDIST GRUP S.R.L.

Cod CUIO: 41247072

Cod IDNO: 1018600004516

Sediul:

MD: 2012

Raionul(municipiul): 105, DDF BUIUCANI

Cod CUATM: 0120, SEC.BUIUCANI

Strada: Mitropolit Gavriil Banulescu-Bodoni nr.25 of.33

Activitatea principală: G4646, Comerț cu ridicata al produselor farmaceutice

Forma de proprietate: 23, Proprietatea statelor străine

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: 068681147

WEB: www.medist.md

E-mail: natalia.mutu@medist.md

Numele și coordonatele al contabilului-șef: DI (dna) Natalia Mutu Tel. 068681147

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

Persoanele responsabile de semnarea situațiilor financiare* Anghel Gabriela-Cristina

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la 31.12.2022

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			
A.	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:			
	2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		

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

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

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

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

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2022 până la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	33578934	29021092
din care:			
venituri din vânzarea produselor și mărfurilor	011	33233405	28497093
venituri din prestarea serviciilor și executarea lucrărilor	012	93698	126338
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	251831	397661
Costul vânzărilor, total	020	21572504	20867803
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	21572504	20867803
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	12006430	8153289
Alte venituri din activitatea operațională	040	34729	135089
Cheltuieli de distribuie	050	309807	118118
Cheltuieli administrative	060	3316071	4920088
Alte cheltuieli din activitatea operațională	070	430627	1931079
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	7984654	1319093
Venituri financiare, total	090	1154867	786797
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din 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	1154867	786797
Cheltuieli financiare, total	100	685067	904528
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	685067	904528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	469800	-117731
Venituri cu active imobilizate și excepționale	120		5290
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		5290
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	469800	-112441
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	8454454	1206652
Cheltuieli privind impozitul pe venit	170	738805	380423
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7715649	826229

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2022 pînă la 31.12.2022

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la 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				
IV.	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere	130	4576184			4576184

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

SITUAȚIA FLUXURILOR DE NUMERAR

de la 01.01.2022 până la 31.12.2022

Anexa 4

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

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

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa 2

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2022

Data prezentarii: 25.05.2023

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 25.05.2023 16:56:13

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

Rechizite bancare:

BC Victoriabank SA, Filiala nr.26 Chișinău

Codul băncii: VICBMD2X469

IBAN (MDL): MD57VI022242600000269MDL

Directoare administrativă: Gabriela Anghel

tel/fax: 022 84 94 95

email: office@medist.md

Web-site: www.medist.md

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Illumina, Inc.
 5200 Illumina Way
 San Diego
 California
 92122
 USA

Facility ID Number: F000219

Holds Certificate No:

MDSAP 660264

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

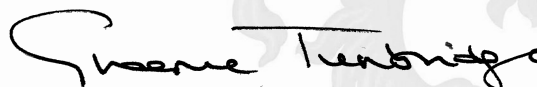
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2016-12-06

Effective Date: 2024-01-18

Expiry Date: 2025-12-05



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

...making excellence a habit.™

Certificate No: **MDSAP 660264**

Registered Scope:

Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.



Original Registration Date: 2016-12-06

Effective Date: 2024-01-18

Expiry Date: 2025-12-05

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 660264**

Location	Registered Activities
ILLUMINA, INC. 5200 ILLUMINA WAY SAN DIEGO CALIFORNIA 92122 USA Facility ID Number: F000219	Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.
ILLUMINA, INC. HAYWARD 25861 INDUSTRIAL BLVD. HAYWARD CALIFORNIA 94545 USA Facility ID Number: F001879	Manufacturing and distribution of instruments used for genetic analysis.



Original Registration Date: 2016-12-06 Effective Date: 2024-01-18 Expiry Date: 2025-12-05

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](#)
To be read in conjunction with the scope above or the attached appendix.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Illumina, Inc.
5200 Illumina Way
San Diego
California
92122
USA

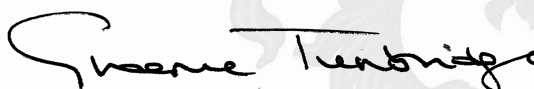
Holds Certificate Number:

FM 565017

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

Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-01-14

Latest Revision Date: 2023-08-07

Effective Date: 2022-12-06

Expiry Date: 2025-12-05

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 565017

Location	Registered Activities
Illumina, Inc. 524 Genomic Drive Madison Wisconsin 53719 USA	Manufacture and process development of components used in reagents for sequencing, genotyping and gene expression products used for genetic analysis.
Illumina, Inc. 5200 Illumina Way San Diego California 92122 USA	Design, Development, Manufacture, Distribution, Installation and Servicing of Sequencing, Genotyping, Gene Expression and PCR - products, instruments and software - used for genetic analysis.
Illumina, Inc. Hayward 25861 Industrial Blvd. Hayward California 94545 USA	Manufacturing and distribution of instruments used for genetic analysis.
Illumina Cambridge Limited (Cambridge) 19 Granta Park Great Abington CB21 6DF United Kingdom	Installation, servicing, technical, product and laboratory support services for Sequencing, Genotyping, Gene Expression (products, instruments and software) used for genetic analysis. Purchasing, planning, procurement and supply chain management. Provision of technical services for customers and internal technical staff in use of instruments and systems. Regional regulatory support. Design and development of clinical software and assays for genetic analysis.

Original Registration Date: 2011-01-14

Latest Revision Date: 2023-08-07

Effective Date: 2022-12-06

Expiry Date: 2025-12-05

Page: 2 of 2

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

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

Wednesday, January 31, 2024

Re: Global Statement for the Minimum Shelf Life for Consumables

To whom it may concern,

Illumina Netherlands BV, having a principal place of business at Steenoven 19, 5626 DK EINDHOVEN, NETHERLANDS warrants that Consumables, other than custom Consumables, will conform to their Specifications until the later of 3 months from the date of shipment from Illumina's warehouse, or any expiration date or the end of the shelf-life pre-printed on such Consumable by Illumina.

In order to avoid any confusion, "Consumable(s)" means Illumina's branded reagents and consumable items that are intended by Illumina to be consumed through the use of Illumina's branded instruments, accessories, or peripherals.

Please do not hesitate to contact customercare@illumina.com with any questions or concerns.

Yours faithfully,


Norbert Keller (Jan 31, 2024 17:21 GMT+1)

Norbert Keller
Sr Director, Supply Chain

On behalf of Illumina Netherlands BV

MiniSeq Reagent Kit

MiniSeq System Reagent kits have a ready-to-use cartridge with two-channel SBS chemistry for cost-efficient sequencing, even for low sample numbers.

[MiniSeq Sequencing System Specification Sheet](#)

[Data sheet](#) | [PDF 5 MB](#)



MiniSeq Rapid Reagent Kit (100 cycles)

20044338

Includes one flow cell and one pre-filled cartridge containi... [View more](#)

— 0 +

[Learn](#) [Order](#)

[Add to cart](#)

PRODUCTS



—

0

+

**MiniSeq High Output Reagent Kit (150-cycles)**

FC-420-1002

Includes one flow cell and one pre-filled cartridge containi... [View more](#)

—

0

+

**MiniSeq High Output Reagent Kit (300-cycles)**

FC-420-1003

Provides kitted reagents for 300 cycles of sequencing, plus dual- indexing support on a High Output run (up to 25M reads). Includes: High Output Reagent Cartridge (300 cycles), Flow Cell, and Hybridization Buffer. [View less](#)

—

0

+

**MiniSeq Mid Output Kit (300-cycles)**

FC-420-1004

Provides kitted reagents for 300 cycles of sequencing, plus ... [View more](#)

—

0

+

FAQs

How many samples can be sequenced on the MiniSeq System at one time?



What is the difference between the run times for MiniSeq Rapid Reagent Kit and the MiniSeq standard reagents?



Does the MiniSeq Rapid Reagent Kit support paired-end reads?



How does the MiniSeq Reagent Kit work?



What is the MiniSeq Reagent Kit used for?



TruSightTM One Sequencing Panels

High-performing
comprehensive panels
targeting disease-associated
regions of the exome

- Extensive coverage of up to 6700 disease-associated genes with a minimum of 20× coverage and two panel options
- Single versatile panel replaces iterative testing with one assay and one workflow
- Intuitive, high-powered annotation and reporting with user-defined gene filtering and report generation



Introduction

The TruSight One Sequencing Panels focus on exonic regions harboring known disease-causing mutations. Focusing on the subset of genes with known associations to inherited disease within the exome enables more efficient variant detection compared to whole-genome or whole-exome sequencing.¹ By combining data from multiple genomic databases and reviewing guidance from industry experts around the world, the TruSight One panels deliver a comprehensive set of disease-associated target regions designed to cover the most commonly ordered disease gene panels.

The TruSight One and TruSight One Expanded panels provide clinical research labs with an affordable solution for managing a diverse assay portfolio. Investigators can choose to analyze all genes on a panel or focus on a specific subset. With a single assay, labs can expand existing menus, streamline workflows, or create an entire portfolio of sequencing options.

TruSight One Sequencing Panel

Genomic targets with disease associations were identified in the Human Gene Mutation Database (HGMD),² the Online Mendelian Inheritance in Man (OMIM) catalog,³ GeneReviews,⁴ previously developed Illumina TruSight

sequencing panels,⁵ and from direct input by industry experts (Figure 1). The TruSight One Sequencing Panel covers 12 Mb of genomic content, including > 4800 genes associated with specific clinical phenotypes. This enables researchers to focus their time and resources on genes with known disease associations.

TruSight One Expanded Sequencing Panel

The TruSight One Expanded Sequencing Panel was developed under the same guiding principles as the original panel with further optimization to improve coverage in regions known to show suboptimal performance. The Expanded panel design targets 16.5 Mb of content, including the original > 4800 genes and ~1900 additional genes with new disease associations in the reference databases.

Extensive content coverage

Probe design enables comprehensive coverage

TruSight One Sequencing Panels feature a highly optimized probe design that enables simultaneous analysis of multiple variants. Both panels include over 125,000 probes constructed against the human NCBI37/hg19 reference genome.⁶ TruSight One probes were built using an iterative

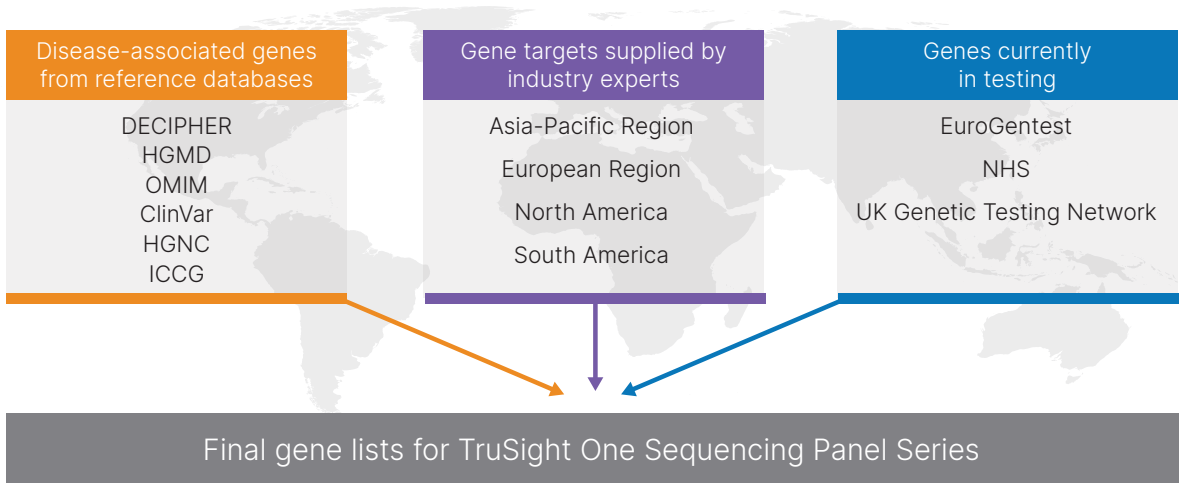


Figure 1: TruSight One Sequencing Panels global gene content contributors—The TruSight One panels focus on exonic regions of the genome with known disease-associated variants. Combining data from multiple public sources makes sure that the panels cover all genes currently reviewed in the clinical research setting.

DECIPHER, Database of Chromosomal Imbalance and Phenotype in Humans using Ensembl Resources; HGNC, HUGO Gene Nomenclature Committee; ICCG, International Collaboration for Clinical Genomics (ICCG); NHS, National Health Service (NHS).

design process with functional testing to ensure optimal performance and depth of coverage. The result is $\geq 20\times$ coverage on 95% of the target regions in the panel (Table 1).*

The 80-mer probes target Illumina DNA Prep with Enrichment libraries with ~300 bp mean fragment sizes and 150–220 bp insert sizes, enriching a broad footprint of bases beyond the midpoint of the probe (Figure 2).⁷

Table 1: TruSight One Sequencing Panel specifications

Parameter	TruSight One	TruSight One Expanded
Cumulative target region size	12 Mb	16.5 Mb
No. of target genes	4811	6704
No. of target exons	~62,000	~86,000
Probe size	80-mer	80-mer
No. of probes	125,395	183,809
Fragment size	150–220 bp	150–220 bp
Minimum coverage ^a	$\geq 20\times$	$\geq 20\times$
Average coverage	$> 100\times$	$> 100\times$
^a . 95% of target regions typically covered at $> 20\times$ (higher percent coverage possible with fewer samples per run).		

* Percentage is calculated by averaging the mean coverage for each exon not each base.

Table 2: Recommended sample throughput for TruSight One Sequencing Panels

	No. of samples per run ^a by instrument and kit configuration			
	MiSeq System v3 reagents	NextSeq 550 System Mid output	NextSeq 550 System High output ^c	NextSeq 2000 System P3 flow cell
TruSight One Panel	3	12	36	96
TruSight One Expanded Panel ^b	1	7	24	66

^a. Up to 2 × 150 bp read length; based on 100× mean coverage of targeted content.
^b. Higher throughput available on the NovaSeq™ 6000 System (96 samples per run, S1 flow cell) for TruSight One Expanded Panel.
^c. Similar throughput can be achieved with NextSeq 1000 and NextSeq 2000 Systems with P2 flow cells.

Therefore, in addition to covering the main exon regions, the panels cover exon-flanking regions, which can provide important biological information (eg, splice sites, regulatory regions).

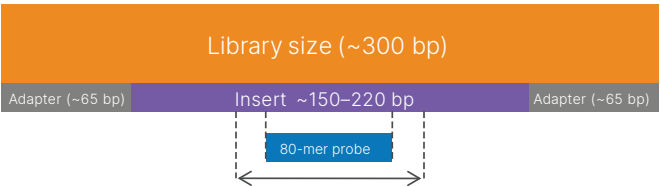


Figure 2: TruSight One probe footprint—With a 300-bp DNA library (insert size of 150–220 bp), the probe will enrich a broad footprint of bases beyond its midpoint.

Compatible with a range of sequencing instruments

The TruSight One panels are ideal for use on Illumina benchtop sequencing systems. Table 2 provides recommended sample throughput for the MiSeq™, NextSeq™ 550, and NextSeq 2000 Systems. No matter the Illumina sequencing system, the TruSight One panels consistently yield high depth of coverage. Because the TruSight One panels focus sequencing on a subset of the genome (eg, genes with phenotype associations), these genes, or target regions, can be sequenced with a high depth of coverage and deliver high-confidence results (Table 3).

Table 3: High depth of coverage with TruSight One Sequencing Panels

	Uniformity of coverage	Target coverage at				Read depth per sample (reads passing filter)
		1×	10×	20×	50×	
TruSight One Panel	95.3%	99.1%	98.3%	97.6%	94.7%	22M
TruSight One Expanded Panel	96.8%	99.4%	98.9%	98.6%	97.5%	33M

Streamlined, fully supported workflow

Each step in the TruSight One Panel workflow, from library preparation to final data analysis, is optimized to provide a streamlined DNA-to-data experiment in just two days (Figure 3).[†] TruSight One Panels are sold as modular kits of enrichment oligos only. Panels integrate seamlessly with the Illumina DNA Prep with Enrichment, (S) Tagmentation Kits and Illumina DNA UD Indexes (sold separately) for library preparation. The modular approach provides greater flexibility for sample processing.

Simple, efficient library preparation

A key component of Illumina DNA Prep with Enrichment is On-bead tagmentation (Figure 4), which uses bead-bound transposomes to mediate a uniform tagmentation reaction. This strategy provides several significant advantages:

- For genomic DNA inputs ≥ 50 ng, accurate quantification of the initial DNA sample is not required as insert fragment size is not affected, saving time and costs associated with kits and reagents
- On-bead tagmentation eliminates the need for separate DNA fragmentation steps, saving time and costs associated with related consumables
- For genomic DNA inputs of 50–1000 ng, saturation-based DNA normalization eliminates the need for individual library quantification and normalization steps before enrichment
- A novel 90-minute single-hybridization protocol enables enrichment in less than four hours

[†] Average time for a targeted gene panel. Times may vary according to run configurations.

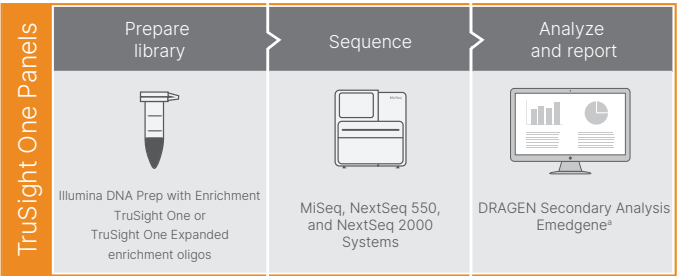


Figure 3: The Illumina TruSight One workflow provides a solution for every step, from library preparation to data analysis and data reporting.

a. Emedgene is available as an optional software platform for germline DNA analysis that is compatible with any library preparation method to enable streamlined, user-defined data interpretation and report generation for research workflows.

Fast enrichment workflow

Illumina DNA Prep with Enrichment is compatible with liquid-handling systems for automating library prep. In addition, the TruSight One workflow uses a unique pre-enrichment sample pooling strategy that reduces the number of enrichment reactions needed. This strategy uses integrated sample barcodes, which supports pooling of up to 12 samples for a single enrichment pulldown. These efficiencies reduce the overall library preparation time to 6.5 hours with ~2 hours of hands-on time. Furthermore, master-mixed reagents coupled with plate-based protocols allow simultaneous processing of multiple reactions. Prepared libraries are loaded on to a flow cell for sequencing in the appropriate instrument.

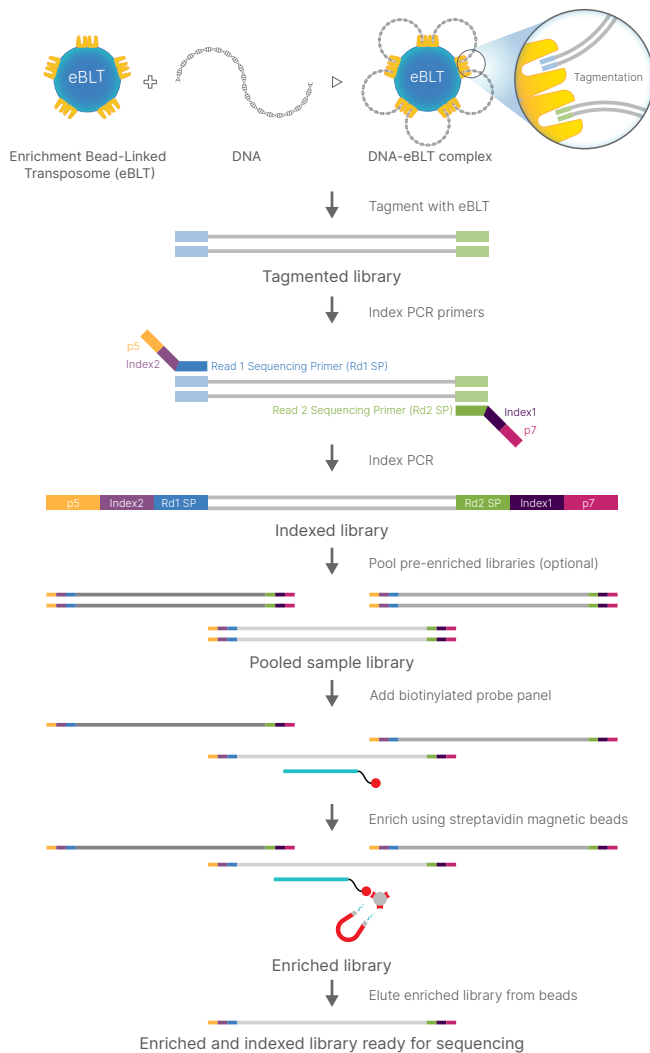


Figure 4: TruSight One and Illumina tagmentation chemistry—
The TruSight One enrichment oligos work with Illumina on-bead tagmentation chemistry to provide a fast, simple method for enrichment of targeted genes. The workflow combines library preparation and target enrichment steps and can be completed in 1.5 hours.

Comprehensive analysis and reporting

For comprehensive TruSight One data analysis, interpretation, and reporting, Illumina offers Emedgene. Emedgene is an optional software tool for research workflows that integrates with BaseSpace™ Sequence Hub and Illumina Connected Analytics to access run monitoring, run metrics, and automated sequencing data upload. It includes cloud-based access to the DRAGEN™ (Dynamic Read Analysis for GENomics) secondary analysis, enabling accurate, comprehensive, and efficient secondary analysis workflows for NGS.

Additional benefits with Emedgene analysis include:

- Streamlined interface with explainable AI (XAI) for highly efficient variant prioritization
- Customizable automation defined by the user for standardization of workflows
- Integrated workflow with DRAGEN secondary analysis and Illumina Connected Analytics for completely automated data movement
- Compatible analysis across hereditary condition applications and assay types (eg, panels, virtual panels, whole-exome sequencing, and whole-genome sequencing)
- Collaboration-ready platform with option to form private, secure networks

Powered by the DRAGEN platform

Emedgene is powered by DRAGEN secondary analysis. Fundamental features of the DRAGEN platform address common challenges in genomic analysis, such as lengthy compute times and massive volumes of data. Without compromising accuracy, the DRAGEN platform delivers quickness, flexibility, and cost efficiency, enabling labs of all sizes and disciplines to do more with their genomic data.

Intuitive, high-powered interpretation

Customers report that Emedgene regularly saves 50–75% of their data interpretation time through efficient report generation.⁸ Emedgene combines multiple features to power user-defined interpretation, including an always up-to-date annotation and knowledge graph; XAI for transparent, evidence-backed, automated rankings

of potentially causative variant(s) for samples; variant visualization; variant curation; user-defined automation; and more to promote efficient and informed variant interpretation. Emedgene was designed for an intuitive user experience to support users in realizing their optimal impact and efficiency towards their mission.

Panel-based filtering with Emedgene

Emedgene is compatible across hereditary disease assay options for germline analysis, including panels, exomes, and genomes. Additionally, Emedgene enables users to bioinformatically create “virtual panels” from TruSight One Sequencing Panels or other NGS data types, such as whole-exome or whole-genome sequencing (Figure 5). This approach enables labs to standardize multiple assays on a single workflow, simplifying and streamlining lab operations. Also, standardization on a backbone assay removes the need to update and change the assay to add more genes over time and facilitates efficient reanalysis of more genes when needed.

Edit Gene List	
Gene List Name	
TruSight One Expanded	
Candidate Genes	
This gene list includes 4908 genes	
A	
A2M NCBI: 2	AAGALT NCBI: 13447
AAGT NCBI: 17140	AAAS NCBI: 6055
AAGC NCBI: 71	AAGC2 NCBI: 34732
AAGB NCBI: 7079	AANAT NCBI: 15
AAR1 NCBI: 17203	AARS NCBI: 10527
ABCA1 NCBI: 28554	ABCA2 NCBI: 28
ABCA3 NCBI: 28	ABCA4 NCBI: 21
ABCA5 NCBI: 28	ABCA6 NCBI: 28
ABCA7 NCBI: 28	ABCA8 NCBI: 28
ABCA9 NCBI: 28	ABCA10 NCBI: 28
ABCA11 NCBI: 28	ABCA12 NCBI: 28
ABCA13 NCBI: 28	ABCA14 NCBI: 28
ABCA15 NCBI: 28	ABCA16 NCBI: 28
ABCA17 NCBI: 28	ABCA18 NCBI: 28
ABCA19 NCBI: 28	ABCA20 NCBI: 28
ABCA21 NCBI: 28	ABCA22 NCBI: 28
ABCA23 NCBI: 28	ABCA24 NCBI: 28
ABCA25 NCBI: 28	ABCA26 NCBI: 28
ABCA27 NCBI: 28	ABCA28 NCBI: 28
ABCA29 NCBI: 28	ABCA30 NCBI: 28
ABCA31 NCBI: 28	ABCA32 NCBI: 28
ABCA33 NCBI: 28	ABCA34 NCBI: 28
ABCA35 NCBI: 28	ABCA36 NCBI: 28
ABCA37 NCBI: 28	ABCA38 NCBI: 28
ABCA39 NCBI: 28	ABCA40 NCBI: 28
ABCA41 NCBI: 28	ABCA42 NCBI: 28
ABCA43 NCBI: 28	ABCA44 NCBI: 28
ABCA45 NCBI: 28	ABCA46 NCBI: 28
ABCA47 NCBI: 28	ABCA48 NCBI: 28
ABCA49 NCBI: 28	ABCA50 NCBI: 28
ABCA51 NCBI: 28	ABCA52 NCBI: 28
ABCA53 NCBI: 28	ABCA54 NCBI: 28
ABCA55 NCBI: 28	ABCA56 NCBI: 28
ABCA57 NCBI: 28	ABCA58 NCBI: 28
ABCA59 NCBI: 28	ABCA60 NCBI: 28
ABCA61 NCBI: 28	ABCA62 NCBI: 28
ABCA63 NCBI: 28	ABCA64 NCBI: 28
ABCA65 NCBI: 28	ABCA66 NCBI: 28
ABCA67 NCBI: 28	ABCA68 NCBI: 28
ABCA69 NCBI: 28	ABCA70 NCBI: 28
ABCA71 NCBI: 28	ABCA72 NCBI: 28
ABCA73 NCBI: 28	ABCA74 NCBI: 28
ABCA75 NCBI: 28	ABCA76 NCBI: 28
ABCA77 NCBI: 28	ABCA78 NCBI: 28
ABCA79 NCBI: 28	ABCA80 NCBI: 28
ABCA81 NCBI: 28	ABCA82 NCBI: 28
ABCA83 NCBI: 28	ABCA84 NCBI: 28
ABCA85 NCBI: 28	ABCA86 NCBI: 28
ABCA87 NCBI: 28	ABCA88 NCBI: 28
ABCA89 NCBI: 28	ABCA90 NCBI: 28
ABCA91 NCBI: 28	ABCA92 NCBI: 28
ABCA93 NCBI: 28	ABCA94 NCBI: 28
ABCA95 NCBI: 28	ABCA96 NCBI: 28
ABCA97 NCBI: 28	ABCA98 NCBI: 28
ABCA99 NCBI: 28	ABCA100 NCBI: 28

Figure 5: Customizable virtual panels—Emedgene offers the capability to create virtual panels from a subset of genes, either by adding genes individually or as a batch.

Summary

The Illumina TruSight One workflow provides a comprehensive DNA-to-data solution for the clinical research environment. Using the TruSight One or the TruSight One Expanded Sequencing Panels, researchers can quickly sequence > 4800 genes with known clinical phenotype association. With the intuitive and

comprehensive rare and other genetic disease insights and report solution from Emedgene, the comprehensive TruSight One data set can deliver customized subpanels responsive to specific areas of research and can provide an efficient, effective solution for genetic disease analysis.

Learn more

[TruSight One Sequencing Panels](#)

[Emedgene](#)

Ordering information

Enrichment oligos	Catalog no.
TruSight One Sequencing Combo (15 samples)	20042621
TruSight One – Enrichment Oligos only (6 enrichment reactions)	20029227
TruSight One Expanded – Enrichment Oligos only (6 enrichment reactions)	20029226
Library preparation kits	Catalog no.
Illumina DNA Prep with Enrichment, (S) Tagmentation (96 samples)	20025524
Illumina DNA Prep with Enrichment, (S) Tagmentation (16 samples)	20025523
Illumina DNA Prep, (S) Tagmentation (96 samples)	20025520
Illumina DNA Prep, (S) Tagmentation (16 samples)	20025519
Indexes	Catalog no.
Illumina DNA/RNA UD Indexes Set A, Tagmentation (96 Indexes, 96 Samples)	20091654
Illumina DNA/RNA UD Indexes Set B, Tagmentation (96 Indexes, 96 Samples)	20091656
Illumina DNA/RNA UD Indexes Set C, Tagmentation (96 Indexes, 96 Samples)	20091658
Illumina DNA/RNA UD Indexes Set D, Tagmentation (96 Indexes, 96 Samples)	20091660

References

1. Montaut S, Tranchant C, Drouot N, et al. [Assessment of a Targeted Gene Panel for Identification of Genes Associated With Movement Disorders](#). *JAMA Neurol*. 2018;75(10):1234-1245. doi:10.1001/jamaneurol.2018.1478.
2. Stenson PD, Mort M, Ball EV, et al. [The Human Gene Mutation Database \(HGMD®\): optimizing its use in a clinical diagnostic or research setting](#). *Hum Genet*. 2020;139(10):1197-1207. doi:10.1007/s00439-020-02199-3
3. McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University (Baltimore, MD), Online Mendelian Inheritance in Man (OMIM). omim.org. Accessed August 31, 2023.
4. Adam MP, Mirzaa GM, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2023. Available from: ncbi.nlm.nih.gov/books/NBK1116/. Accessed October 4, 2023
5. Illumina. TruSight One Sequencing Panels. illumina.com/products/by-type/clinical-research-products/trusight-one.html. Accessed August 31, 2023.
6. Kent WJ, Sugnet CW, Furey TS, et al. [The human genome browser at UCSC](#). *Genome Res*. 2002;12(6):996-1006. doi:10.1101/gr.229102.
7. Illumina. [Optimizing coverage for targeted resequencing technical note](#). Accessed August 31, 2023.
8. Greenwood Genetic Center. GGC Reduces Turn Around Time on Genomic Analysis by 75% With Emedgene's AI Platform. ggc.org/in-the-news-app/ggc-reduces-turn-around-time-on-genomic-analysis-by-75-with-emedgenes-ai-platform. Published September 12, 2019. Accessed September 22, 2023.



1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com

© 2023 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners.
For specific trademark information, see www.illumina.com/company/legal.html.
M-GL-02149 v1.0

Illumina DNA Prep with Enrichment

Fast, integrated workflow
for a wide range of target
enrichment applications

- Provides a time-saving solution that is 85% faster than standard Illumina library prep and enrichment
- Enhances library preparation efficiency with integrated protocols for blood and saliva
- Enables advanced study designs in cancer research, genetic disease research, and whole-exome sequencing



Introduction

The Illumina DNA Prep with Enrichment solution combines versatile, simple, and fast library prep and enrichment functionality for targeted enrichment and exome sequencing applications. It offers extraordinary flexibility for input type and amount (Table 1), and a wide range of supported enrichment sequencing applications encompassing custom panels, fixed panels, and whole-exome sequencing from Illumina or third-party vendors.

Illumina DNA Prep with Enrichment uses innovative bead-based chemistry incorporating a simplified, single hybridization step (Figure 1). With the Illumina DNA Prep with Enrichment workflow, DNA extraction can be processed directly from fresh blood and saliva samples using the Flex Lysis Reagent Kit and Saliva Lysis Protocol, respectively, for additional time savings.

Table 1: Illumina DNA Prep with Enrichment specifications

Parameter	Specification
DNA input type	gDNA, whole blood, saliva, DNA extracted from formalin-fixed, paraffin-embedded (FFPE) tissue
DNA input verified ^a	10–1000 ng
Sample multiplexing	384 unique dual indexes (UDIs)
Pre-enrichment pooling ^b	1-plex or 12-plex verified and supported
Supported sequencing systems	All Illumina systems
Total workflow time ^c	~6.5 hours

a. DNA inputs as low as 10 ng are possible, but will not provide saturation-based DNA normalization.
b. Other enrichment plexities are possible, but have not been verified. Additional optimization may be required and optimal results are not guaranteed.
c. Includes library preparation, enrichment, and library normalization/pooling steps.

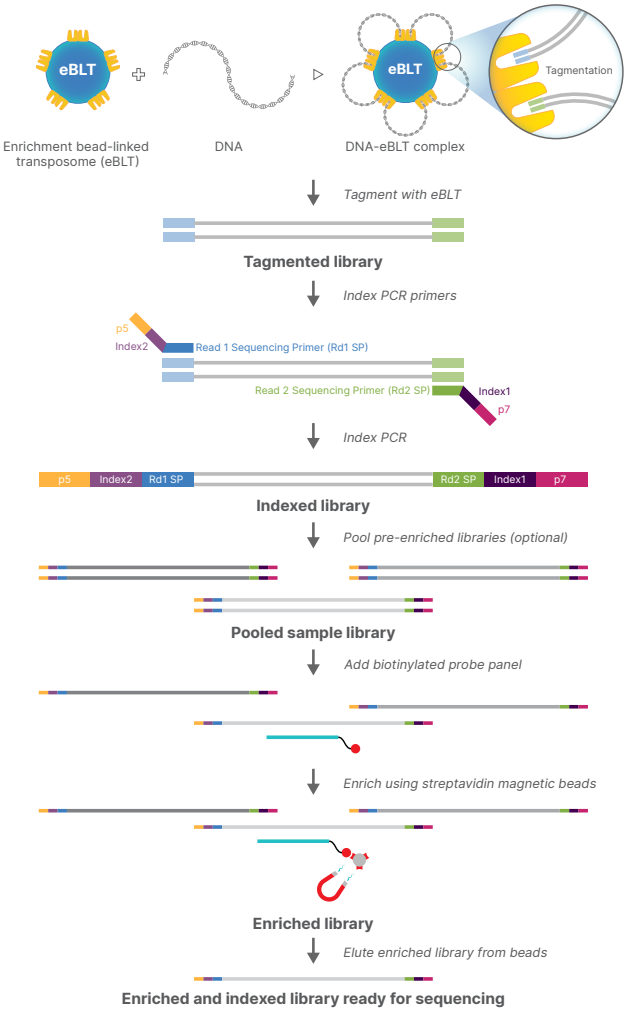


Figure 1: Illumina tagmentation chemistry—A uniform tagmentation reaction mediated by eBLTs followed by a single hybridization reaction enables a fast and flexible workflow.

Fast and flexible library preparation and enrichment workflow

A key component of the Illumina DNA Prep with Enrichment solution is on-bead tagmentation, which uses bead-bound transposomes to mediate a uniform tagmentation reaction. This strategy provides several significant advantages:

- For gDNA inputs ≥ 50 ng, accurate quantitation of the initial DNA sample is not required, as insert fragment size is not affected, saving time and costs associated with kits and reagents
- On-bead tagmentation eliminates the need for separate DNA fragmentation steps, saving time and costs associated with related consumables
- For gDNA inputs of 50–1000 ng, saturation-based DNA normalization eliminates the need for individual library quantitation and normalization steps before enrichment
- Novel 90-minute single hybridization protocol enables enrichment in less than four hours

Fastest Illumina enrichment workflow

The Illumina DNA Prep with Enrichment solution supports liquid-handling systems for library prep automation and produces a workflow with the fewest number of steps and the fastest total workflow time in the Illumina enrichment portfolio (Figure 2, Table 2).

Integrated DNA Input

DNA extraction can be processed directly from whole blood or saliva samples. The optional Flex Lysis Reagent Kit, optimized and validated for using whole blood samples and Illumina DNA Prep with Enrichment, is integrated into the workflow for maximum efficiency. The lysis protocols feature bead-based reagents and require less than 30 minutes of hands-on time.

Optimized performance across Illumina sequencing systems

The robust and straightforward Illumina DNA Prep with Enrichment solution yields reliable results across all Illumina sequencing systems by providing > 90% on-target reads, > 95% uniformity, and a low PCR duplicate rate (Table 3). Illumina DNA Prep with Enrichment is compatible with various Illumina enrichment panels and is optimized for use on low-, mid-, and high-throughput systems (Figure 3, Table 4).

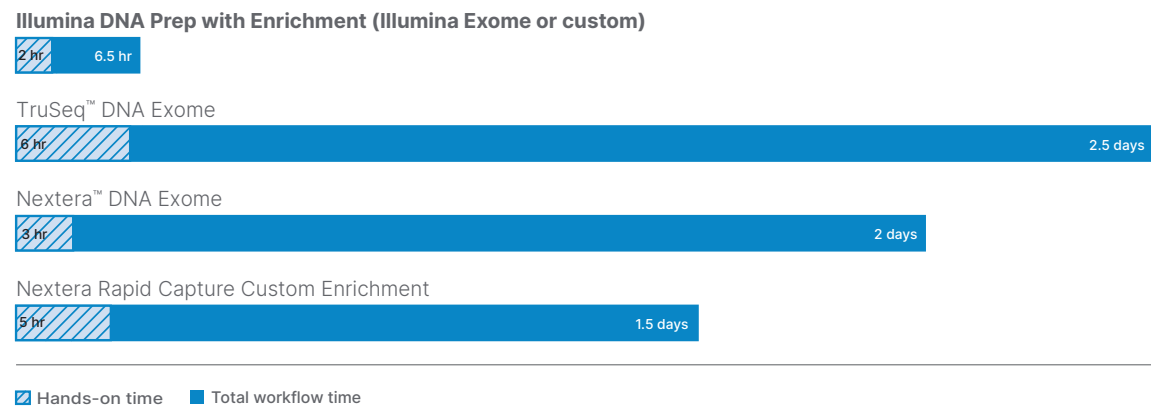


Figure 2: Illumina DNA Prep with Enrichment delivers the fastest Illumina enrichment workflow—Workflow times are based on processing 12 samples at 12-plex enrichment. Times may vary depending on equipment used, number of samples processed, automation procedures, or user experience.

Table 2: Comparison of Illumina enrichment workflows

	Illumina DNA Prep with Enrichment	TruSeq DNA Exome	Nextera DNA Exome	Nextera Rapid Capture Custom Enrichment
Integrated DNA option ^a	✓	—	—	—
Flexible, broad DNA input range	✓	—	—	—
Library normalization included ^b	✓	—	—	—
FFPE compatible	✓	✓	—	—
DNA input	10–1000 ng	100 ng	50 ng	50 ng
Total library prep and enrichment time ^c	~6.5 hr	2.5 days	2 days	1.5 days
Insert size ^d	150–220 bp	150 bp	150–220 bp	230 bp
Sample index sets	384 unique dual indexes	24 single indexes, 96 dual indexes	24 single indexes, 96 dual indexes	24 single indexes, 96 dual indexes

a. Integrated lysis protocols available for blood and saliva.

b. Library normalization occurs with ≥ 50 ng gDNA input.

c. Total library prep and enrichment time includes library preparation, library normalization/pooling, and enrichment.

d. Degraded FFPE DNA may result in smaller insert sizes.

Table 3: Performance comparison across Illumina enrichment workflows^a

Parameter ^b	Illumina DNA Prep with Enrichment	Illumina DNA Prep with Enrichment	Illumina DNA Prep with Enrichment	TruSeq DNA Exome	Nextera DNA Exome
Panel	Illumina Exome Panel ^c	Exome Panel X	Exome Panel Y	Illumina Exome Panel	Illumina Exome Panel
Panel size	45 Mb	39 Mb	33 Mb	45 Mb	45 Mb
Probe size	80 bp	120 bp	120 bp	80 bp	80 bp
Padded read enrichment (on-target) ^d	85%	91%	91%	85%	75%
Fragment length median	~200 bp	~200 bp	~200 bp	~150 bp	~200 bp
Coverage at 20×	93%	96%	97%	90%	85%
Uniformity of coverage ^d	95%	97%	98%	85%	85%
Read depth per sample ^e	30M CPF	25M CPF	20M CPF	40M CPF	40M CPF
SNV precision	99%	99%	99%	99%	99%
SNV recall	94%	94%	95%	89%	91%

a. Data represents example comparison data. Actual performance specifications may vary depending on read depth and sample type.

b. The analysis was run on 48 samples (all NA12878 Coriell samples) per condition. Data analysis was performed using the Enrichment BaseSpace™ App.

c. [Illumina DNA Prep with Exome 2.5 Enrichment](#) is the recommended solution for human exome sequencing.

d. See the BaseSpace™ App User Guide² for additional details.

e. CPF, clusters passing filter.



Figure 3: Optimized performance across Illumina sequencing systems—The Illumina DNA Prep with Enrichment solution is compatible with all Illumina sequencing systems, including the high-performance systems shown here. Low-throughput systems including the iSeq™ 100, MiniSeq™, and MiSeq™ Systems are also compatible with Illumina DNA Prep with Enrichment.

Table 4: Sample throughput per flow cell with Illumina DNA Prep with Enrichment^a

iSeq 100 System		MiniSeq System		MiSeq System			NextSeq 550 System				
		Mid	High	v2	v2 Nano/Micro	v3	Mid	High			
Fixed panels											
TruSight™ One	NR	NR	2	1	0/0	3	12	36			
TruSight One Expanded	NR	NR	1	0	0/0	1	7	24			
TruSight Cancer	4	8	24	12	1/4	24	96	384			
TruSight Hereditary Cancer	4	8	24	12	1/4	24	96	384			
Custom panels											
2000 probes	8	16	50	30	2/8	50	260	384			
5000 probes	2	4	12	8	1/2	12	65	200			
10,000 probes	1	2	6	4	0/1	6	33	100			
NextSeq 550 System		NextSeq 2000 System		NovaSeq 6000 System				NovaSeq X Series			
Mid	High	P2	P3	SP	S1	S2	S4	1.5B	10B	25B	
Exome panel ^b	~4	~12	~10	~30	~20	~41	~104	~250	~41	~250	~750 ^c
a. Mid, mid output; High, high output; NR, not recommended.											
b. Exomes assume ~8 Gb per sample to achieve 100× coverage.											
c. 384 unique dual indexes are available.											

Accurate data

Illumina DNA Prep with Enrichment produces highly uniform and consistent insert sizes across a wide DNA input range, delivering uniform and consistent library yields.¹ It also provides high coverage uniformity and padded read enrichment for custom, fixed, and exome panels (Figure 4). Illumina DNA Prep with Enrichment enables accurate single nucleotide variant (SNV) (Figure 5, Table 3) and insertion/deletion (indel) recall and precision, as compared to other Illumina enrichment solutions.

DNA enrichment for a broad range of applications

By combining exceptional enrichment performance and the proven accuracy of Illumina sequencing by synthesis (SBS) chemistry, the Illumina DNA Prep with Enrichment solution supports both fixed and custom panels of varying sizes, including those designed for whole-exome sequencing, for advanced study designs in a variety of areas (Figure 6). Furthermore, Illumina DNA Prep with Enrichment is compatible with Illumina and third-party enrichment probes/panels, enabling content portability for increased flexibility.

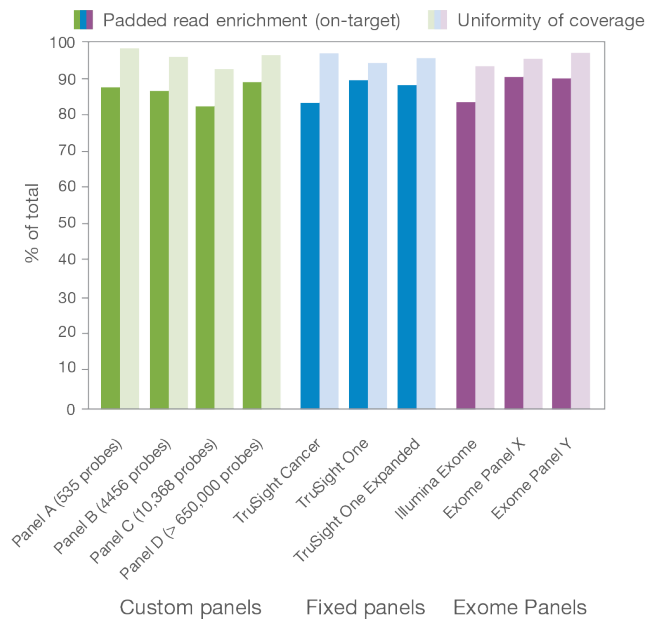


Figure 4: High coverage uniformity and padded read enrichment—Illumina DNA Prep with Enrichment provides high coverage uniformity and on-target padded read enrichment for custom, fixed, and exome panels.

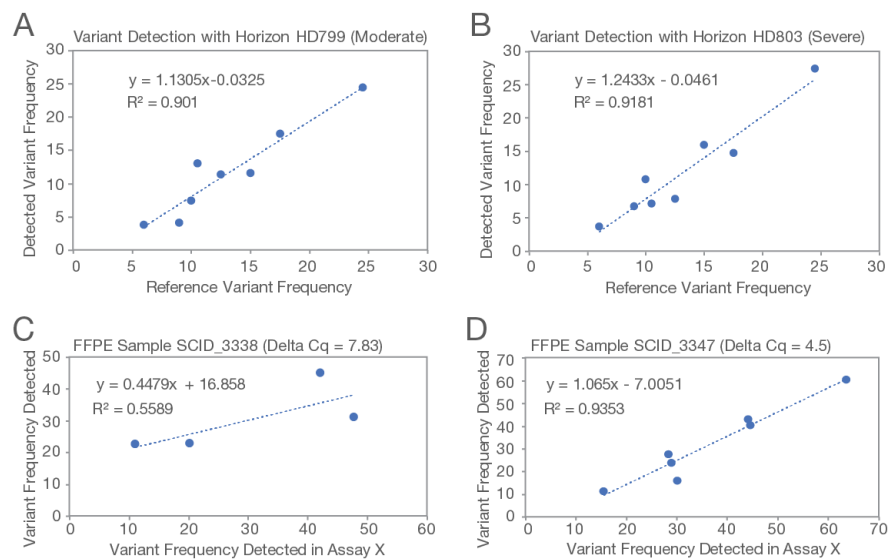


Figure 5: Accurate variant calling—Illumina DNA Prep with Enrichment provides low abundance somatic variant calling for (A, B) cell line FFPE control human reference DNA samples and (C, D) real-world FFPE samples with observed variant frequency showing significant correlation with frequencies from an orthologous sequencing assay.

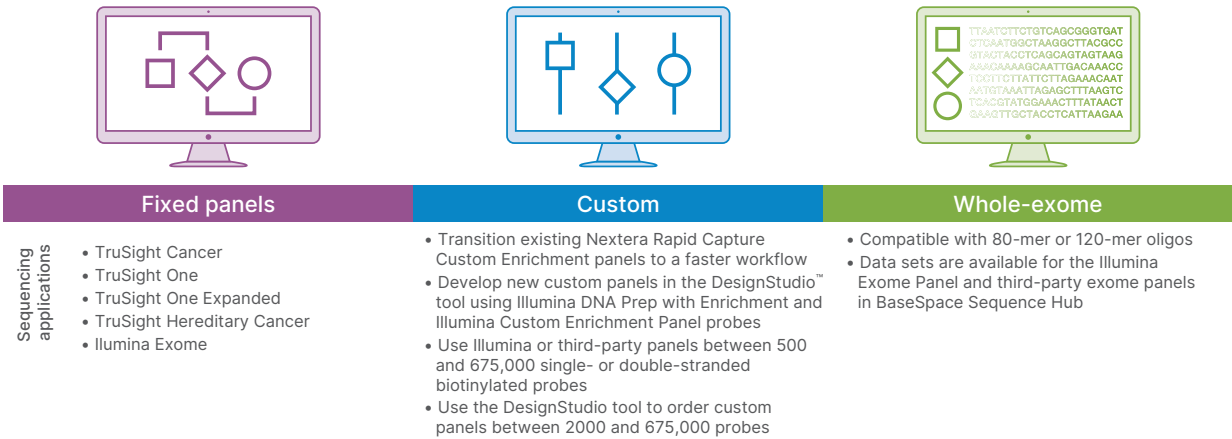


Figure 6: Broad range of applications with Illumina DNA Prep with Enrichment—Illumina DNA Prep with Enrichment supports a broad range of applications, including custom panels, fixed panels, and exome panels.

Summary

Illumina DNA Prep with Enrichment features the fastest workflow in the Illumina enrichment portfolio. The user-friendly, automation-compatible solution supports users of all experience levels and provides a common workflow for a variety of experimental designs, including fixed panels, custom panels, and whole-exome sequencing. On-bead tagmentation enables use of a wide range of DNA input amounts and various sample types. Illumina DNA Prep with Enrichment is compatible with Illumina and third-party enrichment probes/panels, enabling content portability. The innovative Illumina DNA Prep with Enrichment solution combined with the power of Illumina SBS chemistry provides an optimal targeted enrichment and exome sequencing experience.

Learn More

[Illumina DNA Prep with Enrichment](#)

[On-bead tagmentation](#)

References

1. Illumina. Illumina DNA Prep Data Sheet. illumina.com/content/dam/illumina/gcs/assembled-assets/marketing-literature/illumina-dna-prep-data-sheet-m-gl-10373/illumina-dna-prep-data-sheet-m-gl-10373.pdf. Updated 2022. Accessed August 17, 2023.
2. Illumina. BWA Enrichment v2.1 BaseSpace App Guide. support.illumina.com/content/dam/illumina-support/documents/documentation/software_documentation/basespace/basespace-bwa-enrichment-v2-1-app-guide-15050958-01.pdf. Updated 2016. Accessed September 22, 2023.

Ordering information

Product	Catalog no.
Illumina DNA Prep with Enrichment, (S) Tagmentation (96 samples)	20025524
Illumina DNA Prep with Enrichment, (S) Tagmentation (16 samples)	20025523
Flex Lysis Reagent Kit	20018706
Illumina DNA/RNA UD Indexes Set A, Tagmentation (96 indexes, 96 samples)	20091654
Illumina DNA/RNA UD Indexes Set B, Tagmentation (96 indexes, 96 samples)	20091656
Illumina DNA/RNA UD Indexes Set C, Tagmentation (96 indexes, 96 samples)	20091658
Illumina DNA/RNA UD Indexes Set D, Tagmentation (96 indexes, 96 samples)	20091660
TruSight Cancer (8 enrichment reactions)	FC-121-0202
TruSight One (6 enrichment reactions)	20029227
TruSight One Expanded (6 enrichment reactions)	20029226
TruSeq Hereditary Cancer (8 enrichment reactions)	20029551
Illumina Custom Enrichment Panel	20025371



1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com

© 2023 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners.
For specific trademark information, see www.illumina.com/company/legal.html.
M-GL-02147 v1.0

Illumina DNA Prep

A fast, integrated workflow for preparing libraries for use in a wide range of sequencing applications.

Illumina DNA Prep ▼

Data sheet | PDF < 1 MB | 7 versions



~3-4 hr (...)

Assay time



1-1.5 hr

Hands-on time

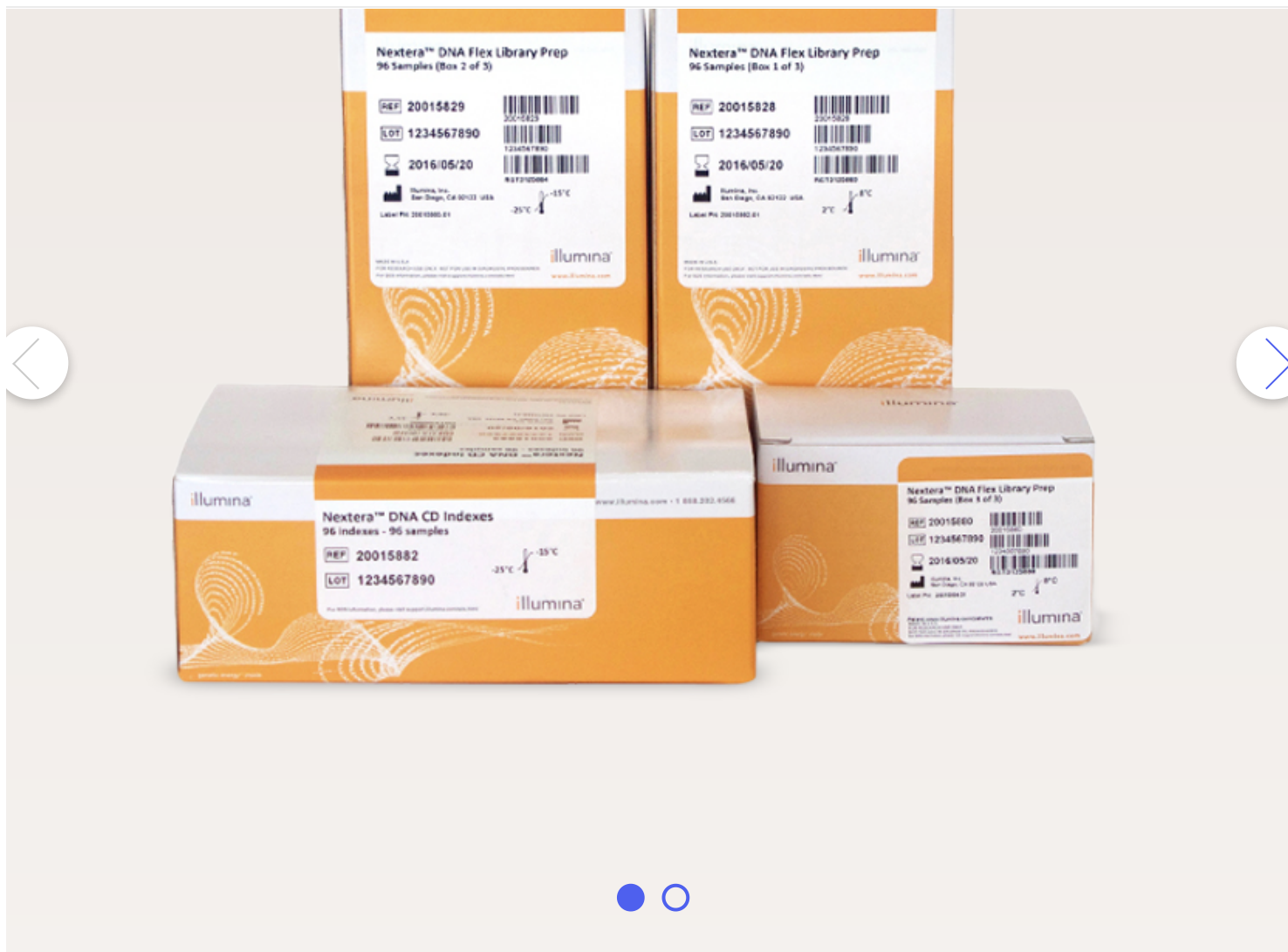


1-500 ng ...

Input quantity

[See full details in the specifications table](#)

PRODUCTS



Nextera DNA Flex products are now called Illumina DNA Prep. The (M) designation denotes a bead-linked transposome that generates an insert size of ~350bp. We recommend ordering the Illumina DNA/RNA UD Indexes Sets A-D (20091654, 20091656, 20091658, 20091660). The IDT for Illumina DNA/RNA UD Indexes Sets A-D (20027213, 20027214, 20042666, 20042667) are being discontinued; the last order date is January 30th, 2025.

[View all](#)

[Library prep](#)

[Index adapters](#)

[Services](#)

[Accessory products](#)

illumina

Order Status

PRODUCTS

☆

illumina DNA Prep, (M) Tagmentation (24 Samples, IPB)

20060060

Includes reagents for preparing 24 libraries. illumina Purif... [View more](#)

—

0

+

☆

illumina DNA Prep, (M) Tagmentation (96 Samples, IPB)

20060059

Includes reagents for preparing 96 libraries. illumina Purif... [View more](#)

—

0

+

Index adapters (9)

☆

illumina® DNA/RNA UD Indexes Set A, Tagmentation (96 Indexes, 96 Samples)

20091654

illumina® DNA/RNA UD Indexes Set A, Tagmentation (96 Indexes, 96 Samples) Includes 96, 10 bp indexes sufficient for labeling 96 samples. Purchase library prep and enrichment reagents and probe panels separately. [View less](#)